Exhibit 1

Calculation of Damages and Penalties for the State of Montana

Declaration of Raymond S. Hartman

I. Introduction and Overview

1. My name is Raymond S. Hartman. I am Director and President of Greylock McKinnon Associates (GMA), an economic consulting and litigation support firm located in Cambridge, Massachusetts. Since I have previously described my qualifications to this Court, I will not repeat them here.

2. I have been asked by Counsel to the State of Montana to review the Complaint in this matter;[1] to review the allegations regarding fraudulent pricing practices on the part of Defendants; and to describe the formulaic methodologies I would use to calculate both the damages to the State and its consumers if the alleged fraudulent pricing practices are proved and the penalties to the Defendants arising from those fraudulent practices.

3. The fraudulent pricing practices specifically alleged of twenty-one Defendant drug manufacturers[2] are characterized as the "AWP Inflation Scheme."[3] Through the alleged "AWP Inflation Scheme" (or "AWP Scheme"), Defendant manufacturers fraudulently increased the AWPs of selected drugs (denoted by NDCs) above the provider acquisition costs (ACs) for which the AWPs were a market signal.[4] Defendants reported the inflated AWPs to the standard national price compendia (*First DataBank (FDB), Red Book* and *Blue Book*), and the industry based reimbursement amounts on those AWPs. Since providers acquired the drugs at acquisition cost (AC) while payors (Medicare, Medicaid, private Third-Party Payers (TPPs), and consumers) paid for the drugs at reimbursement rates based on the AWPs, the increased "spreads" (AWP – AC) caused by the AWP Scheme increased the profits earned by the providers of the drugs (pharmacies, physicians) at the expense of the payors. The increased profits induced providers to move market share of the relevant drugs, the *raison d'etre* of the AWP Scheme to the drug manufacturers.[5]

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[1] State of Montana's Second Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003 (hereafter, *Complaint*).

[2] Identified and discussed in detail in the *Complaint* in ¶¶ 214-602. I have been instructed by Counsel to exclude the GSK Group from my analysis.

[3] *Complaint*, ¶¶ 5-10.

[4] Market reliance upon reported AWPs is discussed in ¶¶ 169-172 of the *Complaint*.

[5] A more complete discussion of the fraud and its market effects are developed in ¶¶ 173-213 of the *Complaint*.

4. The relevant Plaintiffs in this matter for whom damages are alleged include, but are not limited to,[6] the following:

a) The State of Montana

- For pharmaceutical reimbursements under Medicaid (see *Complaint*, ¶¶ 15, 159-163)
- For pharmaceutical reimbursements under Medicaid for "dual eligibles" under Medicare (see *Complaint*, ¶ 158)
- For pharmaceutical reimbursements by State employees (see *Complaint*, ¶ 16)
- For pharmaceutical payments made by State agencies (see *Complaint*, ¶ 17)

b) Montana consumers

- Those consumers making drug coinsurance payments under Medicare Part B (see *Complaint*, ¶ 20)
- Those consumers making coinsurance payments under a private third-party payer plan (see *Complaint*, ¶ 20)
- Those consumers without prescription drug insurance coverage making payments out of pocket (see *Complaint*, ¶ 2).

5. The claims for damages and/or financial penalties made by Plaintiffs include, but are not limited to, the following:

a) Restitution for losses incurred by Montana residents as a result of the AWP Scheme (*Complaint*, ¶¶ 654-660);

b) Restitution of the losses suffered by the State of Montana as a result of the AWP Scheme and recovered as civil penalties for deceptive acts or practices in violation of Mont. Code Ann. §§ 30-14-103 (*Complaint*, ¶¶ 662-667);

c) Recovery of inflated Medicaid reimbursements resulting from fraudulent reporting of inflated AWPs, in violation of Mont. Code Ann. § 53-6-160(1) (*Complaint*, ¶¶ 676-678);

d) Payment of a claim for forfeiture, civil penalties, double damages and legal costs for each violation of Mont. Code Ann. § 17-8-231 under the AWP Scheme (*Complaint*, ¶¶ 681-691); and

e) Payment of punitive damages to the State of Montana (*Complaint*, ¶ 693).

6. To date, Defendants have provided incomplete data and insufficient guidance to fully interpret the data that they have provided to allow me to appropriately calculate damages for all the claims identified above. For example, insufficient data and/or insufficient data description were provided by Defendants to appropriately calculate all

[6] Since I have not had sufficient time to fully analyze all discovery materials, there may be additional Plaintiff groups and additional drugs subject to damage calculations that I will be able to address, if asked to, in a Supplementary Declaration. I anticipate that those damage calculations will make use of formulaic methods analogous to those put forward here.

damages for all injured parties alleged under the AWP Inflation Scheme. I develop methodologies for calculating damages alleged under the AWP Scheme and use them where the data permits. However, given my inability to fully analyze the data submitted by Defendants, I have been instructed by Counsel to develop alternative methodologies that allow me to calculate aggregate penalties arising from the violations alleged in the *Complaint,* in the absence of a complete production of data. I reserve the right to supplement my analyses once sufficient data become available. Given the absence of complete information to calculate all damages and penalties for all Plaintiffs injured under the AWP Inflation Scheme, the damages presented in this Declaration are conservative.

7. My Declaration proceeds as follows. In Section II, I conduct the analysis to develop the formulaic methodologies that can be used for calculating the damages and penalties induced by Defendants' conduct. In Section III, I discuss the measurement of specific components of selected formulaic methodologies and the implementation of those methodologies for those groups for which damages and penalties can be calculated. In Section IV, I implement my formulaic methodologies for those drugs, Defendants, and damage/penalty measures for which data are available. Attachment A lists additional materials relied upon and not identified in my declarations previously submitted in this matter.

II. Analysis

A. The Purpose of the Medicaid and Medicare Statutes

8. The Medicaid drug program and the federal and state initiatives to effectuate it have been designed to implement cost-based drug reimbursement. The legislation and regulation enabling the Medicaid drug program have encouraged states to base their payments on Estimated Acquisition Cost (EAC), as reflected in an early Health Care Financing Administration (HCFA) memorandum:

> "The intent of the final Medicaid regulations on drug payment is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to see that their ingredient cost levels are as close as possible to actual acquisition cost."[7]

As part of the process, over time states have come to require the amount allowed (AA) for Medicaid reimbursement be **the lesser of** the possible measures of cost – the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the

[7] HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: "Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." Indeed, in 1976 the Department of Health and Human Services (HHS) implemented drug reimbursement rules articulating upper limits for payments by Medicaid and other programs (45 CFR Part 19). The rules were designed to ensure that the federal government acts as a cost conscious purchaser of drugs. Of the Federal programs involved, these rules have the greatest impact on the Medicaid program. In 1983, the HHS began reviewing the department's drug reimbursement regulations. The revised regulations were published on July 31, 1987 (52 Fed. Reg. 28648).

Usual & Customary amount (U&C) charged by a pharmacy, and the amount billed. Which of these alternative prices has been relevant has depended upon whether the drug being reimbursed is a single-source or multi-source drug.

a) For single-source drugs, State Medicaid agencies have focused primarily on determining the EAC (and the dispensing fee for the drug), since EAC is invariably less than U&C and the amount billed. Expecting that the AWP provided a reasonable signal for ASPs and EACs,[8] "[t]he EAC for most States is [has been] calculated by using the average wholesale prices (AWP) for a drug less a percentage discount."[9]

b) For multi-source drugs, FUL and MAC are relevant. Once a sufficient number of generic drugs have launched, Medicaid can reimburse for drugs under the Federal Upper Limit (FUL) program. FUL can be established only if all versions of a drug product have been classified as therapeutically equivalent (A-rated) by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and at least three suppliers are listed in the current editions of published national compendia. However, FUL is still linked to the AWPs of the related drugs,[10] and this linkage usually limits its ability to constrain prices increases.[11]

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[8] Properly measured, the ASP to a particular group of providers is the EAC of that group of providers. I have addressed the equivalence of ASP and EAC in ¶ 10.b) of my September 3, 2004 Declaration in Support of Class Certification in the MDL AWP litigation; in ¶¶ 42, 47 & 49 and footnotes 21 and 75 of my December 16, 2004 Rebuttal Declaration in the MDL litigation; and in Attachment K to my December 15, 2005 Declaration on Liability and Calculation of Damages in the MDL litigation.

[9] See U.S. Department of Health and Human Services, OIG, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002, p. 1. The report continues (p. 1), "The AWP is the price assigned to the drug by its manufacturer and is compiled by the Red Book, First DataBank, and Medi-Span for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs." After 1984, a variety of discounts off AWP were paid by manufacturers, reducing the retailer acquisition cost. These discounts were reflected in the reimbursement amounts allowed. For examples, by 1997 the OIG found that the average discount below AWP to retailers was 18.30% for brand name drugs; by 2002, the OIG found that the average discount below AWP to retailers was 22%. See ¶¶ 21-24 of Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification. This observed discount was reflected in the percentage off AWP incorporated into state Medicaid reimbursement formulae generally.

See also Stephen W. Schondelmeyer and Marian V. Wrobel, "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report," Abt Associates Inc., prepared for Center for Medicare and Medicaid, 2004, p. 4; the National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Programs," 2000, p. 4-51; and Table D.1 of my September 3, 2004 MDL Declaration is Support of Class Certification, which presents each state's Medicaid reimbursement formula relative to AWP as of 2004.

[10] For example, under 42 CFR 447.332 (b), the FUL price is required to be set at an amount equal to 150 percent of the published price (in *Blue Book*, *Medi-Span* and/or the *Red Book*) for the least costly generic substitute (as purchased by pharmacists in quantities of 100 units (tablets or capsules)). There seems to be conflicting information as to whether FUL is set at 150% of the lowest AWP or at 150% of other prices that are published in national compendia. For example, one OIG report states that it is set off of AWP: "The upper limit amounts are based on 150 percent of AWP for the lowest priced generic equivalent." See *Medicaid Pharmacy – Actual Acquisition Costs of Generic Prescription Drug Products*, Office of Inspector General, Department of Health and Human Services, March 2002, A-06-01-00053 at p. 4. However, in a

9. The Medicare Program has limited its drug reimbursement primarily to physician-administered drugs under Part B. Medicare has also been designed to limit the amounts allowed as reimbursement to the costs incurred by providers (physicians) in acquiring the relevant drugs. In Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification, I summarize some history of the Medicare Program and the fact that its original approach to reimbursement was cost-based; see ¶¶ 5-7 of that Attachment D. In footnotes 13-14 to my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages, I present the formulae for reimbursement rates under Medicare for physician-administered drugs over time. The criteria consistently involve the lesser of the acquisition cost of the physician and AWP less some amount.

10. Hence, Montana's procedures for reimbursement of drug-related claims under Medicaid and Medicare have been designed to guarantee that the amount allowed as reimbursement approximates as nearly as possible the acquisition costs incurred by the providers of those drugs.

B. Implications of the AWP Inflation Scheme for Drugs Reimbursed Under Medicaid and Medicare

11. To the extent that the alleged AWP Scheme was effectuated by Defendants, the Scheme would have revealed itself in an "excessively" large spread or deviation between an inflated AWP and the acquisition cost of (or sale price to) the relevant providers, for which the AWP is generally taken as a signal.[12] This inflation affected all purchasers of the relevant pharmaceuticals. However, I focus here on the effects of reimbursement under Medicaid and Medicare.

12. As noted in the *Complaint* (at ¶ 170), the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) affirms that the "government sets reimbursement with the expectation that the data provided are complete and accurate." Specifically,

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CMS response by Mark McClellan to another OIG report (*How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List*, Office of Inspector General, Department of Health and Human Services, September 2005, OEI-03-05-00350), he states: "Federal regulation (42 CFR Section 447.332) requires the FUL amount to be 150 percent of the published price for the least costly therapeutic equivalent using data from all available national compendia. The FUL system selects the lowest price of average wholesale price (AWP), wholesale acquisition cost (WAC), or direct price (DP), as reported by the national compendia, to arrive at the FUL price" (at p. 13). Invariably, however, EAC is less than 150% of any of these list prices.

[11] Since Montana does not have a state MAC, this price alternative does not limit Medicaid reimbursement rates. See Table D.1 of Attachment D to my September 3, 2004 Declaration in Support of Class Certification.

[12] Methods for calculating overcharge damages induced by the "AWP Inflation Scheme" have been identified and implemented previously in the MDL AWP matter and in the Connecticut AWP matter. See the Declaration of Raymond S. Hartman in Support of Class Certification, September 3, 2004 and the Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005, both *In re Pharmaceutical Industry Average Wholesaler Price Litigation*; and Calculation of Damages to Connecticut for State Expenditures under the Medical Assistance Programs, Declaration of Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, January 19, 2006 and Expert Disclosure, Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, November 1, 2005.

> "Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. ...
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> Where appropriate, manufacturers' reported prices [therefore] should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products. ... Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements."[13]

13. Defendants are alleged to have distorted the pricing information upon which government programs rely, with the specific intention of artificially inflating spreads.[14]

> "The 'spread' is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the 'spread', it controls its customer's profit.
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> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at '95 percent of average wholesale price.' ...Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
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> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customers from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a

[13] US DHHS, OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, April, 2003. pp. 11-12; cited in *Complaint*, ¶ 170.

[14] *Ibid.*, pp. 26-27; cited in *Complaint*, ¶ 171.

manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product."

14. For purposes of this discussion, I use ASP to denote the average sales price to the relevant class of trade (e.g., retail pharmacies, physicians), which is equivalent to the acquisition cost (AC) of that class of trade when properly measured (see footnote 8 above). While the "spread" is often measured using the AWP and the ASP,[15] it can also be measured as the "spread" or difference between the reimbursement rates that are related to the AWPs and the ASPs which measure provider acquisition costs.

For purposes of this analysis, I make use of the latter definition of spread. I focus upon the spreads between the amounts allowed to providers as drug reimbursement under the Medicaid and Medicare Programs relative to costs at which those providers acquire those drugs. I have been advised by Counsel that if these spreads are larger than allowed by the relevant statute(s), the AWP Scheme led to excessive reimbursement for drug claims. I can calculate the overcharge damages arising from that artificial AWP inflation. I can also determine whether the amounts allowed as reimbursement constitute an excessive amount deceptively charged to and/or falsely claimed in Medicaid and Medicare reimbursement claims.

C. Calculation of Overcharge Damages Under Medicaid and Medicare Arising from the AWP Inflation Scheme

15. Under Medicaid and Medicare, the amount allowed (AA) as reimbursement is related formulaically to the actual (and allegedly artificially inflated) AWP.[16] Specifically, for a given claim, AA = "AWP – x%" + df[17] = (100% – x%)*AWP + df = p*AWP + df for any x%,[18] where the dispensing fee is designated as df and where p =

[15] For example, it can be expressed as (AWP – ASP)/ASP, (AWP – ASP)/AWP, AWP/ASP, or (AWP – ASP). I have addressed these other formulations in my earlier MDL analyses before this Court and in my Connecticut analysis.

[16] As discussed below, the methodology accommodates the reliance upon FUL, U&C or amount billed when they are the basis for AA in the claims data.

[17] Note that I use industry nomenclature to designate reimbursement off AWP as "AWP less some percent (x%)", which really means (100% - x%)*AWP.

[18] According to CMS materials dated June 2004, the reimbursement formulation for self-administered drugs in Montana is AWP – 15% under Medicaid, for both branded and generic drugs. The dispensing fee (df) is $4.70. According to that source, Montana has no MAC; see Table D-1, Attachment D to my September 3, 2004 MDL Declaration in Support of the Certification of Class. From 1991 through June 2002, I understand that the reimbursement formula was AWP – 10%. Note that the *Complaint*, at ¶ 162, suggests that Montana does have a MAC, which diverges from the CMS information in my Table D-1. While this divergence may suggest the need for further scrutiny, if the claims are based upon a state MAC, they will be reflected in the average AA calculated from the claims data.

The amount allowed under Medicare is AWP – x%, where x% is designated over time as delineated in footnote 13 to my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages.

(100 – x)%.[19] Denote the but-for allowed amount as $AA^{but\text{-}for}$.[20] The difference between AA and $AA^{but\text{-}for}$ can be used to calculate overcharge damages as follows.

16. For each year of the period alleged to be subject to the AWP Inflation Scheme, State claims data summarize total number of claims and total dollar reimbursements paid by the State under the Medicaid Program and for drugs reimbursed for dual-eligibles (payment of Medicare supplemental insurance amounts (20%) for physician-administered drugs) by NDC and/or by J-Code. For a given NDC or J-Code, those data would reflect the following:

(1a) Actual Reimbursements = $\Sigma_i AA_i * q_i = \Sigma_i (p*AWP + df)_i * q_i = (p*AWP + df)*Q$,

where Actual Reimbursements is the total dollar amount of claims paid in a given year; Σ_i is the summation of the allowed amount$_i$ (AA_i) times the number (q_i = quantity$_i$) of claims (alternatively the units reimbursed per claim) reimbursed at AA_i; and Q is the total claims or total units reimbursed by the State at an average allowed amount of $AA^{avg} = (p*AWP + df)$.[21]

Had these reimbursements been made at the but-for allowed amount per claim i ($AA^{but\text{-}for}{}_i$), the total reimbursements that should have been paid by the State in a given year would have been,

(1b) But-For Reimbursements = $\Sigma_i AA^{but\text{-}for}{}_i * q_i = (AA^{but\text{-}for\text{-}avg})*Q$,

where the total number of units is assumed to be the same in the but-for and actual worlds.

Having calculated But-For Reimbursements, the damages to the State for reimbursements for drug j of Defendant k are

(1c) Overcharge Damages$_{jk}$ = Actual Reimbursements$_{jk}$ – But-For Reimbursements$_{jk}$

$$= \Sigma_i AA_i * q_i - \Sigma_i AA^{but\text{-}for}{}_i * q_i$$

$$= (AA^{avg} - AA^{but\text{-}for\text{-}avg})Q.$$[22]

17. Aggregate overcharge damages (1c) can be calculated for all units of drug j sold by Manufacturer k and reimbursed by the State as a whole for the Damage Period as a whole; alternatively, it can be calculated for some subset of NDCs of drug j for some subset of State reimbursements for some sub-period of the Damage Period. The use of Equation (1c) is particularly straightforward. The State has data for Actual

[19] Of course, in the actual calculations the percentages are denoted as follows: 100% = 1.00; 15% = 0.15; 10% = 0.10; etc.

[20] Which would be related to a but-for non-inflated AWP as $AA^{but\text{-}for} = AWP^{but\text{-}for} - x\% + df = (100\% - x\%)*AWP^{but\text{-}for} + df = p*AWP^{but\text{-}for} + df$.

[21] The state data summarize reimbursement for all claims. Hence, if some claims are determined by FUL, U&C or the amount billed (all of which I understand are related to AWP), the AA for those claims are specific to that definition and AA^{avg} reflects those claims.

[22] And if we make use of a but-for non-inflated AWP, Overcharge Damages$_{jk}$ = $(p*AWP + df)*Q - (p*AWP^{but\text{-}for} + df)*Q$.

Reimbursements$_{jk}$ for all relevant drugs and Defendant manufacturers, for the relevant Damage Period, for Medicaid and Medicare program reimbursements. The But-For Reimbursements are determined by statute.

D. Calculation of Penalties for Deceptive Practices and False Claims Under the AWP Inflation Scheme

18. Under Count II (¶¶ 662-667) of the *Complaint,* the claim is made for restitution of losses suffered by the State of Montana as a result of the AWP Scheme. Defendants conduct as alleged constitutes deceptive acts or practices in violation of Mont. Code Ann. § 30-14-103 for those transactions in which the AWP was inflated; and for which Defendant manufacturer failed to disclose material facts that the AWP exceeded the average of the wholesale price based upon a good faith and reasonable estimate; and that the Defendant manufacturer knowingly made false representations by representing that the AWP was an accurate reflection of the average wholesale price. Pursuant to Mont. Code Ann. § 30-14-142(2), the *Complaint* states that the Court can assess civil penalties of $1,000 from each defendant for each willful violation of Mont. Code Ann. § 30-14-103.

19. Under Count IV (¶¶ 682-691) of the *Complaint*, a claim for forfeiture, civil penalties, double damages and legal cost pursuant to Mont. Code Ann. § 17-8-231 is made in ¶ 691. Accordingly, it is claimed (¶ 691.C) each defendant must forfeit the entirety of their claims and pay (i) civil penalties of $2,000 per false claim, (ii) double the damages sustained by the State as a result of the false claim, and (iii) the State's legal costs incurred in connection with this action.

20. I have been directed by Counsel to assume that penalties of $3,000 can be assessed for each claim submitted for reimbursement under Medicaid and Medicare that was subject to a deceptive practice and was false.[23] The number of such claims can be calculated as follows.

21. As noted in ¶ 8 above, the allowed amount (AA) under Medicaid is to be the lesser of {the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the Usual & Customary amount (U&C) charged by a pharmacy, or the amount billed}. Likewise, as noted in ¶ 8 above, EAC is invariably the lowest price.

Hence, for any drug reimbursed under Medicaid, I have been instructed by Counsel that liability occurs as a matter of law if $AA_{jk} > EAC_{jk}$. Furthermore, as discussed above (see footnote 8), $EAC_{jk} = ASP_{jk}$ to the relevant group of providers (pharmacies, physicians). For self-administered drugs reimbursed under Medicaid, j denotes the NDC of the drug and k denotes the Defendant. For physician-administered drugs, j denotes the NDC or the J-Code and k denotes the Defendant.

22. I have been provided with information from the State sufficient to calculate AA_{jk} by claim, net of the dispensing fee. While I received from Defendants a variety of data

[23] My methodology focuses upon accurately calculating the number of complaints that were deceptive and false. Should I receive alternative direction from the Court regarding the amount of the penalty to be assessed per false and deceptive claim, the calculation of aggregate penalties will be very easy to revise to accommodate those alternative directions. The revised calculation is simple arithmetic.

sets summarizing (to varying degrees of completeness) invoice information, rebates information and other accounting information, I have not received from Defendants sufficient explanation and clarification of these data to accurately calculate the ASP_{jk} by NDC and/or J-Code for most drugs and most Defendants in this matter. Indeed, the data that I have been able to use to analyze liability using ASPs have been developed as part of the MDL AWP litigation addressing the Track 1 Defendants and the Connecticut AWP litigation.

Given this limited ability to make use of discovery materials, I have developed a method to make use of the existing information to draw conclusions regarding liability. Specifically,

a) For claims for reimbursement for single-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC, EAC will be the lesser of the alternative reimbursement bases.[24]
- AWP – (16.6%-20%)[25] = WAC
- I understand that the retail acquisition costs (RAC) is approximately equal to WAC and indeed may be slightly less {that is, RAC (EAC) < WAC}, perhaps 1-2% of AWP.[26] To be conservative, I assume that RAC = EAC ≈ WAC.[27]
- Using the upper bound of these discounts off AWP, if AA > AWP – 20%, AA exceeds EAC.
- Using the lower bound of these discounts off AWP, AA > AWP – 16.6%, AA exceeds EAC.
- Absent a measure of ASP, I let the threshold for liability be AA > AWP – 20%. For sensitivity analysis, I let the threshold for liability be AA > AWP – 16.6%. In each case, if AA exceeds the threshold I conclude AA fraudulently exceeds EAC.

b) For claims for reimbursement for multi-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC; since FUL > EAC; and since Montana does not have a state MAC; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that EACs (i.e., ASPs or RACs) < AWP – (16.6%-66%)[28] over the period 1991-2002.

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[24] The U&C is the "walk-in" price paid by uninsured cash payers; it is usually ≈ AWP.

[25] These discounts off AWP are equivalent to spreads of 20%-25% above WAC. For example, if AWP – 20% = WAC; then AWP (100%-20%) = .80*AWP = WAC; and AWP = 1.25 WAC or WAC + 25%.

[26] See footnote 9 above.

[27] This understanding is corroborated by Defendants' Experts; see footnote 8 above.

- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a reasonable threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, in my calculations in Section IV below, I bound this reasonable threshold by allowing the threshold to be AWP – 20% and AWP – 66%.

c) For claims for physician-administered drugs reimbursed under Medicaid, I conclude the following:

- For those drugs for which I have ASPs and AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC. The ASP may be delineated by NDC or J-Code. Given the time consuming process of performing the cross-walk for multi-source physician-administered drugs reimbursed by J-Code, I do not analyze liability for physician-administered drugs once they go generic, even if I have ASP data for a generic drug of a Defendant. Note that this exclusion will make my calculation of penalties conservative.
- Since the Amount Billed, the U&C and FUL > EAC; and since Montana does not have a state MAC; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that for single-source drugs, physician acquisition cost (PAC) is at most equal to WAC and often much less (i.e., PAC < AWP – (20%-75%).
- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a conservative threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, in my calculations in Section IV, I bound this threshold by allowing the threshold to be AWP – 20% and AWP – 66%.
- Because Montana began to rely upon Medicare data for AWPs for Medicaid-reimbursed drugs dispensed under J-Codes and because Medicare shifted in 2005 to reimbursement based upon ASP, I do not include any reimbursement claims for 2005.

[28] Since evidence indicates that EAC < 16.6%-20% for brand name drugs, it is well known that the discount off AWP for generic drugs will be greater than 16.6% - 20%. For example, by 1997, the OIG found that the average discounts below AWP at retail were 42.45% for generics. By 2002, OIG found these discounts from AWP to be even deeper, approximately 66%. See ¶¶ 21-24 of Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification. Both of these OIG reports used a sampling of states. The earlier report used a sample of ten states and the District of Columbia; the later report used a sample of 8 states. Montana was one of the states chosen in both of the samples. See *Medicaid Pharmacy – Actual Acquisition Costs of Generic Prescription Drug Products*, Office of Inspector General, Department of Health and Human Services, March 2002, A-06-01-00053.

23. For the analysis of Medicaid reimbursement for dual-eligible Medicare claims, the available medical claims summarize reimbursement for the 20% Medicare coinsurance by J-Code. For these reimbursements, I conclude the following:[29]

- For those drugs for which I have ASPs and AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC. The ASPs will be delineated by J-Code. Given the time consuming process of performing the cross-walk for multi-source physician-administered drugs reimbursed by J-Code, I do not analyze liability for physician-administered drugs once they go generic. Note that this exclusion will make my calculation of penalties conservative.
- Evidence demonstrates that for single-source drugs, physician acquisition cost (PAC) is at most equal to WAC and often much less (i.e., PAC < AWP – (20%-75%).
- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a reasonable threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, I bound this threshold by allowing the threshold to be AWP – 20% and AWP – 66%.
- Again, because Medicare shifted in 2005 to reimbursement based upon ASP, I do not include any reimbursement claims for 2005, if they are present in the data.

III. Selected Issues Arising with Implementation of the Formulaic Methodology for Damage Calculation

A. Reimbursement for Drug Claims Under Montana's Medicaid Program

24. The reliance of Montana's Medicaid Program upon AWP for reimbursement resembles Medicaid reimbursement in most states.[30] The *Complaint* (¶162) states

> "The Montana Medicaid program *presently* reimburses for outpatient drugs on the basis of the lower of (i) estimated acquisition cost ("EAC") or the maximum allowable costs ("MAC" [which is calculated as FUL by Montana – the Federal Upper Limit]) plus a dispensing fee … or (ii) the provider's usual and customary charge [U&C]."[31]

25. However, the EAC is consistently less than U&C (the "walk-in" price charged to uninsured cash payers, which is usually ≈ AWP), MAC (= FUL) (which is 150%* the lowest AWP or WAC) and AWP – x% (10% or 15%). Thus, while legislation and

[29] I express these comparisons in terms of AA and EAC, understanding that the amounts recorded by the State are actually 20% thereof.

[30] See Attachment D generally and Table D-1 specifically of my September 3, 2004 Declaration in Support of Class Certification in this matter.

[31] See Transmittal and Notice of Approval of State Plan Material for Montana, Attachment 4.19B, Methods and Standards,TN 00-008, effective date October 1, 2000. Definition of MAC is discussed in footnote 10 above.

regulation of the Medicaid drug program has encouraged states to base their payments on Estimated Acquisition Cost (EAC = ASP), state Medicaid programs have not. Instead, they have been forced to base their reimbursements on AWP.[32] As a result, Defendant Manufacturers' AWP Scheme and reliance by the State upon AWP has caused the State of Montana to be overcharged as follows.

Using the notation of ¶¶ 15-16 above

a) For self-administered drugs "*presently*," $AA = AWP - 15\% + df = (100\% - 15\%)*AWP + df = 0.85*AWP + df$, and $AA^{but\text{-}for} = EAC + df = ASP + df$.

b) For self-administered drugs "*formerly*," $AA = AWP - 10\% + df = 0.90*AWP + df$, and $AA^{but\text{-}for} = EAC + df = ASP + df$.

c) I have been informed by Counsel that the reimbursement formula switched from AWP - 10% to AWP - 15% on July 1, 2002.[33]

d) For physician-administered drugs reimbursed by Montana as a drug claim (and therefore reported by NDC), I assume the same reimbursement formulae.

26. While Montana statutes indicate that the amount allowed on all, or at least substantially all, drug claims is formulaically based on AWP in this fashion, the actual calculation of AA_i, $\Sigma_i AA_i$ and AA^{avg} in Section IV below is based upon the claims themselves. Actual claim amounts are compared with actual ASPs, when those ASPs are available.

27. When ASPs have not been available and I have relied upon the thresholds determined as in ¶¶ 22-23 above, I also rely upon claims data and the thresholds calculated relative to AWPs.

B. Reimbursement for Drugs Reported as Medical Claims Under Montana's Medicaid Program

28. Medicaid reimburses for physician-administered drugs recorded as Medical claims using J-Codes for two groups of patients: i) those patients strictly covered by Medicaid, and ii) those patients covered by Medicare whose 20% co-insurance is covered by Medicaid ("dual eligibles"). Reimbursement formulae and calculation issues for the first set of medically-related drug claims are the same as those discussed above in ¶¶ 24-27 for Medicaid drug claims.

29. Reimbursement formulae and calculation issues for the second set of medically-related drug claims (dual eligibles) are determined by the Medicare reimbursement formulae presented in footnote 13 of my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages. While these claims could be analyzed in a fashion similar to that put forward above, the Montana data for these claims do not disaggregate the 20% drug coinsurance payment from the 20% coinsurance payment for all medical services provided by the physician administering the physician-administered

[32] See ¶ 8 and footnote 9 above.

[33] I have examined the Montana Medicaid Drug Claims and confirmed that the switch in AA to AWP – 15% did occur on July 1, 2002.

drug. I did not have sufficient time to identify the allowed amount AA_i for the drug alone on these claims, in order to calculate overcharges and penalties. For this reason, I do not compare a claimed amount to the AWP of the drug (by J-Code), in order to identify the number of false claims. Likewise, I do not calculate damages or penalties for this group of claims. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

C. Reimbursement for Drug Claims and Medical Claims For State Employees and State Agencies

30. The drugs for which reimbursement was paid based upon AWP by these groups will likewise be categorized as self-administered branded drugs, self-administered generic drugs or physician-administered drugs. Calculation of overcharge damages and the penalties for false and deceptive claims would proceed as above, if I had been provided with claims data for these groups. I was not, and do not therefore calculate overcharge damages or identify the number of false and deceptive claims subject to recovery of penalties. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

D. Reimbursement for Drug Payments Made by Uninsured Consumers

31. The price of drugs to walk-in customers without insurance is understood to be U&C ≈ AWP. Such consumers have been overcharged by the AWP Scheme. I have no data summarizing these reimbursements; hence, I cannot calculate the related damages or penalties. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

E. Analysis of Medicaid Rebates

32. I have not received complete data on Medicaid rebates paid to the State. According to the CMS Medicaid Drug Rebate Program, Medicaid rebates are to be calculated as a fixed percentage of AMP ("Average Manufacturer Price"),[34] which purports to approximate the ASP. For the purposes of the overcharge damage analysis, I assume that AMP is the same in the actual and but-for worlds (since ASP is the same), and therefore the total amount of rebates received by the state is the same in the actual and but-for worlds. As a result, if properly paid in the actual world, Medicaid rebates net

[34] See http://www.cms.hhs.gov/MedicaidDrugRebateProgram; rebates for innovator drugs are set at 15.1% of AMP; and rebates for non-innovator drugs are set at 11% of AMP.

out of the damage calculation.[35] However, if rebates were not paid in the actual world, overcharge damages incurred by the State are higher than those calculated here.[36]

IV. The Calculation of Damages and Recovery of Penalties for False Claims and Deceptive Practices

33. Tables 1-6 summarize the calculations of overcharge damages and the measures of recovery for false claims and deceptive practices, making use of the methodologies presented above.[37]

a) Table 1 presents selected overcharge damages by Defendant and by Drug, when the reimbursement claims provided by Montana are drug claims based upon NDCs. Recall that almost no information was available to me to calculate aggregate overcharge damages. As a result, the sum of overcharge damages in Table 1 is useful for illustration rather than as a basis for recovery for economic injury.

b) Table 2 presents selected overcharge damages by Defendant and by Drug, when the reimbursement claims provided by Montana are medical claims that include reimbursement for drugs by J-Code and provision of physician services by CPT-Code. As with Table 1, almost no information was available to me to calculate aggregate overcharge damages by J-Code, and this sum of overcharge damages is useful for illustration only rather than as a basis for recovery for economic injury.

c) Table 3 summarizes my analysis of claims data for single-source self-administered drugs. It presents information regarding the total number of claims for such drugs by Defendant; it tabulates those claims that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASPs and those identified on the basis of the threshold amounts related to the drugs' AWP. I have allowed for two thresholds: AA > AWP – 16.6% and AA > AWP –

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[35] State reimbursements for Medicaid should net out rebate payments. Specifically, Actual Net Reimbursements = Actual Reimbursements – Actual Rebates. Likewise, But-For Net Reimbursements = But-For Reimbursements – But-For Rebates. Therefore, Overcharge Damages = Actual Net Reimbursements – But-For Reimbursements = (Actual Reimbursements – Actual Rebates) – (But-For Reimbursements – But-For Rebates). However, since ASP and AMP are the same in both the but-for and actual worlds, Actual Rebates = But-For Rebates, and Overcharge Damages = Actual Reimbursements – But-For Reimbursements (as in Equation (1c)).

[36] Using the notation in the preceding footnote, Overcharge Damages = Actual Net Reimbursements – But-For Reimbursements = (Actual Reimbursements – Actual Rebates) – (But-For Reimbursements – But-For Rebates). When rebates are paid in the actual world and by reasonable assumption are the same in the but-for world, the rebates net out of the damage calculation, as above. If however, Actual Rebates = $0 when Actual Rebates should = But-For Rebates > 0, then Corrected Overcharge Damages = (Actual Reimbursements – 0.00) – (But-For Reimbursements – But-For Rebates) = (Actual Reimbursements – But-For Reimbursements) + **But-For Rebates** > my calculated Overcharge Damages = Actual Reimbursements – But-For Reimbursements.

[37] Note that none of these calculations take account of pre-judgment interest. They are therefore conservative.

20%. If AA exceeds the ASP or the threshold, I conclude AA fraudulently exceeds EAC.

d) Table 4 summarizes my analysis of claims data for multi-source self-administered drugs. It presents information regarding the total number of claims for such drugs by Defendant; it tabulates those claims that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASPs and those identified on the basis of the threshold amounts related to the drugs' AWP. While I conclude that the threshold of AWP – 25% is reasonable for the Damage Period as a whole, I bound this threshold by allowing the liability threshold to be AWP – 20% and AWP – 66%.

e) Table 5 summarizes my analysis of claims data for physician-administered drugs reimbursed under Medicaid, excluding claims for "dual eligibles." It presents information regarding the total number of claims for such drugs by Defendant and those that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASP and those identified on the basis of the threshold amounts related to the drugs' AWP. While I conclude that the threshold of AWP – 25% is conservative for the Damage Period as a whole, I bound this threshold by allowing the liability threshold to be AWP – 20% and AWP – 66%.

34. To summarize the results of these Tables, I find (and report where appropriate in Table 6)

a) Given the paucity of data I can effectively use to calculate actual ASPs, I am able to calculate overcharge damages for a *de minimis* number of drugs designated by NDC or J-Code. The measure of aggregate overcharge damages for both sets of drugs found in Tables 1 and 2 is $1.45 million (see Table 6, column 1).

b) The number of claims that are false and subject to deceptive practices is substantial under widely different bounds for reasonable thresholds of calculating the EAC relative to the reported AWP.

- In Table 3, the total number of such claims for single-source self-administered drugs ranges from a low of 6 (for Watson) to a high of 538,359 (for Pfizer) across Defendants. Since the penalty for such deceptive and false practices is $3,000 in total, the amount of the recovery for that penalty is also substantial, ranging from $18,000 (Watson) to $1.6 billion (Pfizer) across Defendants. The total recovery for this class of drugs for this Period ranges from $4.4 billion to $5.9 billion, depending upon the threshold.

- In Table 4, the total number of such claims for multi-source self-administered drugs ranges from 2 (for the Aventis Group) to 96,354 (for Schering-Plough[38]) across Defendants. Again, since the penalty for such deceptive and false practices is $3000 in total, the amount of the recovery for that penalty is also substantial, ranging from $6,000 (for Aventis Group) to $289 million (for

[38] Note that this total includes those based upon comparing the AA with the ASP (86,471) and those based upon comparing the AA with the 66%*AWP threshold (9,883). Dey has the largest number of claims based upon the threshold comparison alone (41,789).

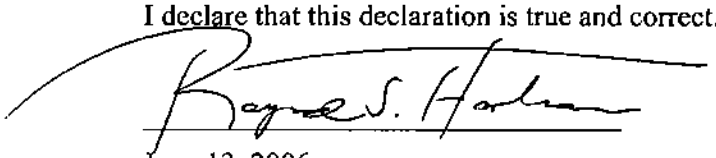
Schering-Plough) across Defendants. The total recovery for this class of drugs for this Period ranges from $395 million to $583 million, depending upon the threshold.

- In Table 5, the total number of such claims for physician-administered drugs ranges from 1 (for Novartis) to 2,408 (for Amgen) across Defendants. The amount of the recovery for that penalty ranges from $3,000 (for Novartis) to $7.2 million (for Amgen) across Defendants. The total recovery for this class of drugs for this Period ranges from $11.5 million to $15.4 million, depending on the threshold.
- In Table 6, the range of penalties based upon the bounds for the yardstick thresholds is $4.77 billion to $6.47 billion (summed over Table 3-5).

35. While the assumptions regarding thresholds for EAC in Tables 3-5 are reasonable, they are assumptions. In Table 7, I present supplemental calculations for the number of false and deceptive claims making no assumption regarding EAC. Instead, I count the number of claims for each type of drug (single-source self-administered, multi-source self-administered and physician-administered) the allowed amount for which exceeds that amount allowed under the Montana Medicaid statute; i.e., AA > AWP – 10% and AA > AWP – 15% for the relevant periods of time (see ¶¶ 24-25 above). Note that I conduct this analysis only for the claims for which I do not have ASPs and therefore have made assumptions about the thresholds for EAC. For those drugs for which I have ASPs, I can relate AA to the EAC = ASP.

For those drugs for which I can calculate ASPs, Table 7 indicates that the allowed amount exceeds the ASP on 16,518 claims for single-source drugs and 87,312 claims for multi-source drugs. Using the statutory reimbursement amounts for those drugs for which I do not have ASPs, I find that the amount allowed exceeds the statutory reimbursement allowance on 388,628 claims for single-source drugs and on 16,270 claims for multi-source drugs. For all claims identified as false and deceptive in Table 7, I find that total penalties are $1.5 billion across Defendants.

I declare that this declaration is true and correct.



June 13, 2006

Attachment A

Additional Materials Relied Upon

Hartman, Raymond, Declaration of Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, January 19, 2006 and Expert Disclosure, Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, November 1, 2005

State of Montana, State of Montana's Second Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, , MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003

U.S. Department of Health and Human Services, OIG, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002

Table 1: Calculation of Overcharge Damages for Selected Drugs Reimbursed Based on NDCs

Defendant	Drug	Total by Drug
AstraZeneca	Pulmicort Respules	38,277
AstraZeneca	Zoladex	54,371
AstraZeneca Total		**$92,648**
Aventis	Anzemet	3,655
Aventis	Taxotere	802
Aventis Group Total		**$4,457**
BMS	Blenoxane	798
BMS	Cytoxan	5,281
BMS	Paraplatin	181
BMS	Taxol	412
BMS	Vepesid	5,580
BMS Group Total		**$12,250**
Johnson & Johnson	Procrit	49,464
Johnson & Johnson	Remicade	16,384
Johnson & Johnson Total		**$65,848**
Pharmacia	Adriamycin	5,249
Pharmacia	Amphocin	311
Pharmacia Group Total		**$5,561**
Schering-Plough	Albuterol	782,048
Schering-Plough	Intron	14,361
Schering-Plough	Proventil	21,729
Schering-Plough	Temodar	18,790
Warrick Pharmaceuticals	Perphenazine	11,003
Schering-Plough Group Total		**$847,939**
Total Overcharges for Selected Drugs		**$1,028,703**

Table 2: Calculation of Overcharge Damages for Selected Drugs Reimbursed Based on J-Codes

Manufacturer	Drug	J-Code	Total by Drug
AstraZeneca	ZOLADEX	J9202	$14,066
Aventis	TAXOTERE	J9170	$245,437
BMS Group	TAXOL	J9265	$50,850
Johnson & Johnson Group	REMICADE	J1745	$6,928
Johnson & Johnson Group	PROCRIT	Q0136	$23,350
Pharmacia	ANZEMET	J1260	$81,563
Total Overcharges for Selected Drugs by J-Code			$425,196

Table 3: Deceptive Trade and False Claims Penalties - Single-Source Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds*[1]			*Penalties (ASP and (AWP - 16.6%))*			*Penalties (ASP and (AWP - 20.0%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshold Analysis	# of Fraudulent Claims Based on (AWP-16.6%)	# of Fraudulent Claims Based on (AWP-20.0%)	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties
Abbott	44,153	0	0	44,153	12,952	14,530	$12,952,000	$25,904,000	$38,856,000	$14,530,000	$29,060,000	$43,590,000
Amgen	4,424	0	0	4,424	3,896	4,262	$3,896,000	$7,792,000	$11,688,000	$4,262,000	$8,524,000	$12,786,000
AstraZeneca	224,548	5,280	5,051	219,268	125,166	189,713	$130,247,000	$260,494,000	$390,741,000	$184,794,000	$389,588,000	$584,382,000
Aventis Group	131,573	39	35	131,534	94,013	117,323	$94,048,000	$188,096,000	$282,144,000	$117,358,000	$234,716,000	$352,074,000
Baxter	292	0	0	292	125	127	$125,000	$250,000	$375,000	$127,000	$254,000	$381,000
Bayer	47,582	0	0	47,582	40,336	44,663	$40,336,000	$80,672,000	$121,008,000	$44,663,000	$89,326,000	$133,989,000
Boehringer Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Braun	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
BMS Group	330,533	645	626	329,888	234,287	283,598	$234,913,000	$469,826,000	$704,739,000	$284,224,000	$568,448,000	$852,672,000
Dey	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Fujisawa Group	1,483	0	0	1,483	963	1,246	$963,000	$1,926,000	$2,889,000	$1,246,000	$2,492,000	$3,738,000
Immunex	30	0	0	30	30	30	$30,000	$60,000	$90,000	$30,000	$60,000	$90,000
Johnson & Johnson	348,519	196	195	348,323	247,561	310,495	$247,756,000	$495,512,000	$743,268,000	$310,690,000	$621,380,000	$932,070,000
Novartis	247,494	0	0	247,494	176,750	220,231	$176,750,000	$353,500,000	$530,250,000	$220,231,000	$440,462,000	$660,693,000
Pfizer	654,287	0	0	654,287	334,584	536,359	$334,584,000	$669,168,000	$1,003,752,000	$536,359,000	$1,076,718,000	$1,615,077,000
Pharmacia Group	40,110	12	12	40,098	22,845	33,410	$22,857,000	$45,714,000	$68,571,000	$33,422,000	$66,844,000	$100,266,000
Schering-Plough Group	141,993	9,920	9,609	132,073	90,149	110,295	$99,758,000	$199,516,000	$299,274,000	$119,904,000	$239,808,000	$359,712,000
Sicor Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	78,278	54,341	74,039	$54,341,000	$108,682,000	$163,023,000	$74,039,000	$148,078,000	$222,117,000
Watson	6	0	0	6	6	6	$6,000	$12,000	$18,000	$6,000	$12,000	$18,000
Total-All Defendants	2,295,305	16,092	15,558	2,279,213	1,436,004	1,942,327	$1,453,562,000	$2,907,124,000	$4,360,686,000	$1,957,885,000	$3,915,770,000	$5,873,655,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 4: Deceptive Trade and False Claims Penalties - Multi-Source Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds*[1]			*Penalties (ASP and (AWP - 20.0%))*			*Penalties (ASP and (AWP - 65.9%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshold Analysis	# of Fraudulent Claims Based on (AWP-20.0%)	# of Fraudulent Claims Based on (AWP-66.0%)	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties
Abbott	15,449	0	0	15,449	7,705	14,020	$7,705,000	$15,410,000	$23,115,000	$14,020,000	$28,040,000	$42,060,000
Amgen	191	0	0	191	178	185	$178,000	$356,000	$534,000	$185,000	$370,000	$555,000
AstraZeneca	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Aventis Group	2	0	0	2	2	2	$2,000	$4,000	$6,000	$2,000	$4,000	$6,000
Baxter	5,352	0	0	5,352	2,391	3,906	$2,391,000	$4,782,000	$7,173,000	$3,906,000	$7,812,000	$11,718,000
Bayer	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Boehringer Group	15	0	0	15	7	9	$7,000	$14,000	$21,000	$9,000	$18,000	$27,000
Braun	3,320	0	0	3,320	1,950	2,576	$1,950,000	$3,900,000	$5,850,000	$2,576,000	$5,152,000	$7,728,000
BMS Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Dey	51,373	0	0	51,373	22,244	41,789	$22,244,000	$44,488,000	$66,732,000	$41,789,000	$83,578,000	$125,367,000
Fujisawa Group	5	0	0	5	5	5	$5,000	$10,000	$15,000	$5,000	$10,000	$15,000
Immunex	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Johnson & Johnson	3,494	881	836	2,613	2,414	2,605	$3,250,000	$6,500,000	$9,750,000	$3,441,000	$6,882,000	$10,323,000
Novartis	1,339	0	0	1,339	1,241	1,337	$1,241,000	$2,482,000	$3,723,000	$1,337,000	$2,674,000	$4,011,000
Pfizer	1,661	0	0	1,661	350	1,448	$350,000	$700,000	$1,050,000	$1,448,000	$2,896,000	$4,344,000
Pharmacia Group	32	8	5	24	17	22	$22,000	$44,000	$66,000	$27,000	$54,000	$81,000
Schering-Plough Group	99,192	86,966	86,471	12,226	4,598	9,883	$91,069,000	$182,138,000	$273,207,000	$96,354,000	$192,708,000	$289,062,000
Sicor Group	5	0	0	5	5	5	$5,000	$10,000	$15,000	$5,000	$10,000	$15,000
TAP	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Watson	41,303	0	0	41,303	1,280	29,235	$1,280,000	$2,560,000	$3,840,000	$29,235,000	$58,470,000	$87,705,000
Total-All Defendants	222,733	87,855	87,312	134,876	44,387	107,027	$131,699,000	$263,398,000	$395,097,000	$194,339,000	$388,678,000	$583,017,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 5: Deceptive Trade and False Claims Penalties - Physician Administered Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds*[1]			*Penalties (ASP and (AWP - 20.0%))*			*Penalties (ASP and (AWP - 66.9%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshold Analysis	# of Fraudulent Claims Based on (AWP-20.0%)	# of Fraudulent Claims Based on (AWP-66.0%)	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties
Abbott	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Amgen	2,422	0	0	2,422	1,616	2,405	$1,616,000	$3,232,000	$4,848,000	$2,408,000	$4,816,000	$7,224,000
AstraZeneca	80	36	36	44	43	43	$79,000	$158,000	$237,000	$79,000	$158,000	$237,000
Aventis Group	440	122	122	318	318	318	$440,000	$880,000	$1,320,000	$440,000	$880,000	$1,320,000
Baxter	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Bayer	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Boehringer Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Braun	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
BMS Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Dey	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Fujisawa Group	47	0	0	47	47	47	$47,000	$94,000	$141,000	$47,000	$94,000	$141,000
Immunex	16	0	0	16	16	16	$16,000	$32,000	$48,000	$16,000	$32,000	$48,000
Johnson & Johnson	960	802	802	158	158	158	$960,000	$1,920,000	$2,880,000	$960,000	$1,920,000	$2,880,000
Novartis	2	0	0	2	1	2	$1,000	$2,000	$3,000	$2,000	$4,000	$6,000
Pfizer	14	0	0	14	14	14	$14,000	$28,000	$42,000	$14,000	$28,000	$42,000
Pharmacia Group	39	0	0	39	39	39	$39,000	$78,000	$117,000	$39,000	$78,000	$117,000
Schering-Plough Group	1,078	0	0	1,078	580	1,078	$580,000	$1,160,000	$1,740,000	$1,078,000	$2,156,000	$3,234,000
Sicor Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
TAP	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Watson	52	0	0	52	52	52	$52,000	$104,000	$156,000	$52,000	$104,000	$156,000
Total-All Defendants	5,150	960	960	4,190	2,884	4,175	$3,844,000	$7,688,000	$11,532,000	$5,135,000	$10,270,000	$15,405,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 6: Summary of Overcharge Damages and Penalties by Defendant and Total

	All Overcharges[1]	*Penalties - Based on Yardstick Threshold Bounds*[2]	
		Lower Bound	Upper Bound
Abbott	$0	$61,971,000	$85,650,000
Amgen	$0	$17,070,000	$20,565,000
AstraZeneca	$106,714	$390,976,000	$584,619,000
Aventis Group	$250,895	$283,470,000	$353,400,000
Baxter	$0	$7,546,000	$12,099,000
Bayer	$0	$121,008,000	$133,989,000
Boehringer Group	$0	$21,000	$27,000
Braun	$0	$5,550,000	$7,728,000
BMS Group	$83,100	$704,739,000	$852,672,000
Dey	$0	$66,732,000	$125,367,000
Fujisawa Group	$0	$3,045,000	$3,894,000
Immunex	$0	$138,000	$138,000
Johnson & Johnson	$98,126	$755,898,000	$945,273,000
Novartis	$0	$533,976,000	$664,710,000
Pfizer	$0	$1,004,844,000	$1,519,463,000
Pharmacia Group	$87,124	$68,754,000	$100,464,000
Schering-Plough Group	$847,939	$574,221,000	$652,008,000
Sicor Group	$0	$15,000	$15,000
TAP	$0	$163,023,000	$222,117,000
Watson	$0	$4,014,000	$87,879,000
Total-All Defendants	$1,453,898	$4,767,315,000	$6,472,077,000

Notes:
1. Tables 1 and 2.
2. Tables 3, 4 and 5.

Table 7: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Statute Change)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Statute Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (10%-15%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (10%-15%)[6]	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Total Penalties
Abbott	59,502	0	0	0	59,502	1,327	1,500	$1,327,000	$2,654,000	$3,981,000	$1,500,000	$3,000,000	$4,500,000	$8,481,000
Amgen	7,037	0	0	0	7,037	1,129	35	$1,129,000	$2,258,000	$3,387,000	$35,000	$70,000	$105,000	$3,492,000
AstraZeneca	224,628	5,316	5,117	0	219,312	25,284	0	$30,401,000	$60,802,000	$91,203,000	$0	$0	$0	$91,203,000
Aventis Group	132,015	161	157	0	131,854	29,368	0	$29,525,000	$59,050,000	$88,575,000	$0	$0	$0	$88,575,000
Baxter	5,644	0	0	0	5,644	54	1,134	$54,000	$108,000	$162,000	$1,134,000	$2,268,000	$3,402,000	$3,564,000
Bayer	47,582	0	0	0	47,582	10,685	0	$10,685,000	$21,370,000	$32,055,000	$0	$0	$0	$32,055,000
Boehringer Group	15	0	0	0	15	0	1	$0	$0	$0	$1,000	$2,000	$3,000	$3,000
Braun	3,320	0	0	0	3,320	0	852	$0	$0	$0	$852,000	$1,704,000	$2,556,000	$2,556,000
BMS Group	330,533	645	626	0	329,888	69,762	0	$70,388,000	$140,776,000	$211,164,000	$0	$0	$0	$211,164,000
Dey	51,373	0	0	0	51,373	0	8,892	$0	$0	$0	$8,892,000	$17,784,000	$26,676,000	$26,676,000
Fujisawa Group	1,535	0	0	0	1,535	285	3	$285,000	$570,000	$855,000	$3,000	$6,000	$9,000	$864,000
Immunex	46	0	0	0	46	16	0	$16,000	$32,000	$48,000	$0	$0	$0	$48,000
Johnson & Johnson	352,973	1,979	997	838	351,094	66,134	667	$67,131,000	$134,262,000	$201,393,000	$1,503,000	$3,006,000	$4,509,000	$205,902,000
Novartis	248,635	0	0	0	248,635	59,344	284	$59,344,000	$118,688,000	$178,032,000	$284,000	$568,000	$852,000	$178,884,000
Pfizer	655,962	0	0	0	655,962	88,598	81	$88,598,000	$177,196,000	$265,794,000	$81,000	$162,000	$243,000	$266,037,000
Pharmacia Group	40,181	20	12	5	40,161	5,912	6	$5,924,000	$11,848,000	$17,772,000	$11,000	$22,000	$33,000	$17,805,000
Schering-Plough Group	242,263	96,886	9,509	86,471	145,377	18,061	2,533	$27,670,000	$55,340,000	$83,010,000	$89,004,000	$178,008,000	$267,012,000	$350,022,000
Sicor Group	5	0	0	0	5	0	0	$0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	0	78,278	12,669	0	$12,669,000	$25,338,000	$38,007,000	$0	$0	$0	$38,007,000
Watson	41,361	0	0	0	41,361	0	292	$0	$0	$0	$292,000	$584,000	$876,000	$876,000
Total-All Defendants	2,523,188	104,907	16,518	87,312	2,418,281	388,628	16,280	$405,146,000	$810,282,000	$1,215,438,000	$103,592,000	$207,164,000	$310,776,000	$1,526,214,000

Notes:
1. Tables 3, 4 and 5.
2. Tables 3 and 5.
3. Table 4.
4. Tables 3, 4 and 5.
5. Table 3. These Totals also include the number of fraudulent claims calculated from the Medical claims data, based on the same statutory thresholds.
6. Table 4.

Exhibit 2

Calculation of Damages and Penalties for the State of Montana

Supplementary Declaration of
Raymond S. Hartman

I. Introduction and Overview

1. My name is Raymond S. Hartman.

2. I have been asked by Counsel to perform a sensitivity analysis to supplement my June 13, 2006 Declaration. The sensitivity analysis allows for the possible effects of data rounding and certain data imprecision when calculating penalties arising from the comparison of Montana Medicaid claims data to statutorily set discounts off AWP. I report the results of this recalculation in Table 7a of this Supplementary Declaration. Table 7a takes Table 7 of my June 13, 2006 Declaration as its point of departure. For ease of exposition, both tables are presented here.

II. The Recalculation of Damages and Recovery of Penalties for False Claims and Deceptive Practices

3. While the assumptions regarding thresholds for the EAC in Tables 3 through 5 of my June 13, 2006 Declaration are reasonable, they are assumptions. In Table 7, I presented supplemental calculations for the number of false and deceptive claims making no assumption regarding EAC. Instead, I counted the number of claims for each type of drug (single-source self-administered, multi-source self-administered and physician-administered) the allowed amount for which exceeded that amount allowed under the Medicaid statute; i.e., AA > AWP – 10% and AA > AWP – 15% for the relevant periods of time. Again, I conducted this analysis only for the claims for which I did not have ASPs and therefore had made (in Tables 3-5) assumptions about the thresholds for EAC.

4. In Table 7 of the June 13, 2006 Declaration, I reported the results of the analysis using a strict application of the statutory language. Specifically, if the allowed amount AA is > AWP – 10% and AA > AWP – 15% for the relevant periods of time, I found the claim false and subject to deceptive trade practices. Using this criterion for the relevant claims (2.42 million in total), I found that 388,628 claims for single-source innovator drugs and 16,280 claims for multi-source drugs exceeded the amount allowed by statute. The total is 404,908. When I included those claims for which I could make a determination by ASP rather than the statutorily-calculated amount, an additional 16,518 claims for single-source innovator drugs and 87,312 claims for multi-source drugs were determined to be false and subject to deceptive trade practices. The total number of claims that were false and subject to deceptive trade practices was 508,738; the total amount of penalties for these claims is $1.53 billion.

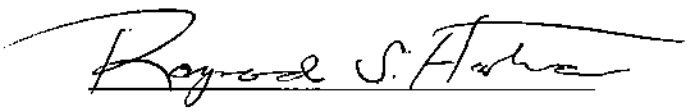
5. The analysis in Table 7 relied upon calculated measures of AWP thresholds and allowed amounts, calculations based upon FDB AWPs which are reported by extended units. Since the allowed amounts on the claims and the AWP thresholds must be expressed in comparable units, rounding to the nearest penny is required for both

components of the comparison. Furthermore, there may be some slight imprecision in the numbers reported. As a result, strict interpretation of the statutory thresholds may suggest an incorrect number of claims as being false and subject to deceptive trade practices. Table 7a provides additional calculations as sensitivity analysis for this possibility.

While I do not analyze systematically the direction of the effect of the rounding and other data issues, I do introduce a calculation that should provide a conservative correction for these data issues. Specifically, I allow for an extra percentage point in the statutory threshold using AWP; that is, if the allowed amount AA is > AWP – 9% and AA > AWP – 14% for the relevant periods of time, I find the claim false and subject to deceptive trade practices.

Using these criteria for those claims (again 2.42 million in total) for which I use these more liberal (to Defendants) thresholds, I find that 8,527 claims for single-source innovator drugs and 922 claims for multi-source drugs exceed the threshold. The total is 9,449. When I include those claims for which I can make a determination based on ASP rather than the statutorily-calculated amount, the additional number of claims does not change; 16,518 claims for single-source innovator drugs and 87,312 claims for multi-source drugs are determined to be false and subject to deceptive trade practices. In this case, the total number of claims that are false and subject to deceptive trade practices is 113,279; the total amount of penalties for these claims is $340 million.

I declare that this declaration is true and correct.



June 20, 2006

Table 7: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Statute Change)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Statute Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (10%-15%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (10%-15%)[6]	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Total Penalties
Abbott	59,602	0	0	0	59,602	1,327	1,500	$1,327,000	$2,654,000	$3,981,000	$1,500,000	$3,000,000	$4,500,000	$8,481,000
Amgen	7,037	0	0	0	7,037	1,129	35	$1,129,000	$2,258,000	$3,387,000	$35,000	$70,000	$105,000	$3,492,000
AstraZeneca	224,626	5,316	5,117	0	219,312	25,264	0	$30,401,000	$60,802,000	$91,203,000	$0	$0	$0	$91,203,000
Aventis Group	132,015	161	157	0	131,854	29,368	0	$29,525,000	$59,050,000	$88,575,000	$0	$0	$0	$88,575,000
Baxter	5,644	0	0	0	5,644	54	1,134	$54,000	$108,000	$162,000	$1,134,000	$2,268,000	$3,402,000	$3,564,000
Bayer	47,582	0	0	0	47,582	10,685	0	$10,685,000	$21,370,000	$32,055,000	$0	$0	$0	$32,055,000
Boehringer Group	15	0	0	0	15	0	1	$0	$0	$0	$1,000	$2,000	$3,000	$3,000
Braun	3,320	0	0	0	3,320	0	852	$0	$0	$0	$852,000	$1,704,000	$2,556,000	$2,556,000
BMS Group	330,533	645	626	0	329,888	69,762	0	$70,388,000	$140,776,000	$211,164,000	$0	$0	$0	$211,164,000
Dey	51,373	0	0	0	51,373	0	8,892	$0	$0	$0	$8,892,000	$17,784,000	$26,676,000	$26,676,000
Fujisawa Group	1,535	0	0	0	1,535	285	3	$285,000	$570,000	$855,000	$3,000	$6,000	$9,000	$864,000
Immunex	46	0	0	0	46	16	0	$16,000	$32,000	$48,000	$0	$0	$0	$48,000
Johnson & Johnson	352,973	1,879	997	836	351,094	66,134	667	$67,131,000	$134,262,000	$201,393,000	$1,503,000	$3,006,000	$4,509,000	$205,902,000
Novartis	248,635	0	0	0	248,635	59,344	284	$59,344,000	$118,688,000	$178,032,000	$284,000	$568,000	$852,000	$178,884,000
Pfizer	655,962	0	0	0	655,962	88,598	81	$88,598,000	$177,196,000	$265,794,000	$81,000	$162,000	$243,000	$266,037,000
Pharmacia Group	40,161	20	12	5	40,161	5,912	6	$5,924,000	$11,848,000	$17,772,000	$11,000	$22,000	$33,000	$17,805,000
Schering-Plough Group	242,263	96,686	9,609	56,471	145,377	18,061	2,533	$27,670,000	$55,340,000	$83,010,000	$89,004,000	$178,008,000	$267,012,000	$350,022,000
Sicor Group	5	0	0	0	5	0	0	$0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	0	78,278	12,669	0	$12,669,000	$25,338,000	$38,007,000	$0	$0	$0	$38,007,000
Watson	41,361	0	0	0	41,361	0	292	$0	$0	$0	$292,000	$584,000	$876,000	$876,000
Total-All Defendants	2,523,168	104,907	16,518	57,312	2,418,261	388,628	16,280	$405,146,000	$810,292,000	$1,215,438,000	$103,592,000	$207,164,000	$310,776,000	$1,526,214,000

Notes:
1. Tables 3, 4 and 5.
2. Tables 3 and 5.
3. Table 4.
4. Tables 3, 4 and 5.
5. Table 5. These Totals also include the number of fraudulent claims calculated from the Medical claims data, based on the same statutory thresholds.
6. Table 4.

Table 7a: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Adjusting for Rounding and Data Issues - Assume Statute Allows AWP - 9% and AWP - 14%)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 9% to AWP - 14%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 13% to AWP - 14%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Statute Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (9%-14%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (9%-14%)[6]	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Deceptive Trade ($1000/claim)	False Claim ($2000/claim)	Total Penalties	Total Penalties
Abbott	59,602	0	0	0	59,602	115	202	$115,000	$230,000	$345,000	$202,000	$404,000	$606,000	$951,000
Amgen	7,037	0	0	0	7,037	12	0	$12,000	$24,000	$36,000	$0	$0	$0	$36,000
AstraZeneca	224,828	5,316	5,117	0	219,312	934	0	$6,051,000	$12,102,000	$18,153,000	$0	$0	$0	$18,153,000
Aventis Group	132,015	161	157	0	131,854	1,552	0	$1,709,000	$3,418,000	$5,127,000	$0	$0	$0	$5,127,000
Baxter	5,644	0	0	0	5,644	0	272	$0	$0	$0	$272,000	$544,000	$816,000	$816,000
Bayer	47,582	0	0	0	47,582	29	0	$29,000	$58,000	$87,000	$0	$0	$0	$87,000
Boehringer Group	15	0	0	0	15	0	0	$0	$0	$0	$0	$0	$0	$0
Braun	3,320	0	0	0	3,320	0	58	$0	$0	$0	$58,000	$116,000	$174,000	$174,000
BMS Group	330,533	645	626	0	329,888	380	0	$986,000	$1,972,000	$2,958,000	$0	$0	$0	$2,958,000
Dey	51,373	0	0	0	51,373	0	14	$0	$0	$0	$14,000	$28,000	$42,000	$42,000
Fujisawa Group	1,535	0	0	0	1,535	3	0	$3,000	$6,000	$9,000	$0	$0	$0	$9,000
Immunex	46	0	0	0	46	11	0	$11,000	$22,000	$33,000	$0	$0	$0	$33,000
Johnson & Johnson	352,973	1,879	997	836	351,094	1,455	193	$2,452,000	$4,904,000	$7,356,000	$1,029,000	$2,058,000	$3,087,000	$10,443,000
Novartis	248,835	0	0	0	248,835	41	0	$41,000	$82,000	$123,000	$0	$0	$0	$123,000
Pfizer	655,962	0	0	0	655,962	3,998	0	$3,998,000	$7,996,000	$11,994,000	$0	$0	$0	$11,994,000
Pharmacia Group	40,161	20	12	5	40,161	11	0	$23,000	$46,000	$69,000	$5,000	$10,000	$15,000	$84,000
Schering-Plough Group	242,263	96,886	9,609	86,471	145,377	6	0	$9,615,000	$19,230,000	$28,845,000	$86,471,000	$172,942,000	$259,413,000	$288,258,000
Sicor Group	5	0	0	0	5	0	0	$0	$0	$0	$0	$0	$0	$0
TAP	78,278	0	0	0	78,278	0	0	$0	$0	$0	$0	$0	$0	$0
Watson	41,361	0	0	0	41,361	0	183	$0	$0	$0	$183,000	$366,000	$549,000	$549,000
Total-All Defendants	2,523,188	104,907	16,518	87,312	2,418,281	8,527	922	$25,045,000	$50,090,000	$75,135,000	$88,234,000	$176,468,000	$264,702,000	$339,837,000

Notes:
1. Tables 3, 4 and 5.
2. Tables 3 and 5.
3. Table 4.
4. Tables 3, 4 and 5.
5. Table 3. These Totals also include the number of fraudulent claims calculated from the Medical claims data, based on the same statutory thresholds.
6. Table 4.

Exhibit 3

Calculation of Damages and Penalties for the State of Nevada

Declaration of Raymond S. Hartman

I. Introduction and Overview

1. My name is Raymond S. Hartman. I am Director and President of Greylock McKinnon Associates (GMA), an economic consulting and litigation support firm located in Cambridge, Massachusetts. Since I have previously described my qualifications to this Court, I will not repeat them here.

2. I have been asked by Counsel to the State of Nevada to review the Complaints in this matter;[1] to review the allegations regarding fraudulent pricing practices on the part of Defendants; and to describe the formulaic methodologies I would use to calculate both the damages to the State and its consumers if the alleged fraudulent pricing practices are proved and the penalties to the Defendants arising from those fraudulent practices.

3. The fraudulent pricing practices specifically alleged of twenty-one Defendant drug manufacturers[2] are characterized as the "AWP Inflation Scheme."[3] Through the alleged "AWP Inflation Scheme" (or "AWP Scheme"), Defendant manufacturers fraudulently increased the AWPs of selected drugs (denoted by NDCs) above the provider acquisition costs (ACs) for which the AWPs were a market signal.[4] Defendants

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[1] I have been instructed by Counsel to respond to the following three complaints:

1) State of Nevada's Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003 (hereafter, *State Complaint*);

2) State of Nevada's First Amended Complaint, *State of Nevada v. Abbott Laboratories, et. al.* Case No. CV 02-00260; Dept. No. 8, In the Second Judicial District Court in and for the County of Washoe, State of Nevada, October 31, 2003 (hereafter *Federal Complaint*); and

3) State of Nevada's Amended Complaint Against Defendant Bayer Corporation, *State of Nevada v. Bayer Corporation*, No. CV 02-00260, Dept. No. 8, In the Second Judicial District Court in and for the County of Washoe, State of Nevada, February 27, 2004 (hereafter *Bayer Complaint*).

Hereafter, reference to all three Nevada complaints will be *Complaints*.

[2] Identified and discussed in detail in the *Complaints*. The *State Complaint* identifies 13 Defendants (Amgen, AstraZeneca, The Aventis Group, The Boehringer Group, Braun, The Fujisawa Group, Immunix, The Johnson & Johnson Group, Novartis, Pfizer, The Schering-Plough Group, The Sicor Group and Watson). I have been instructed by Counsel to exclude the GSK Group from my analysis. The *Federal Complaint* identifies another 7 Defendants (Abbott, Baxter, The BMS Group, Dey, The GSK Group, The Pharmacia Group and Tap). The *Bayer Complaint* identifies Bayer as a Defendant. I have been asked by Counsel to omit from my analysis the following Bayer drugs: Koate HP, Kogenate , Konyne-80, Gamimune N 5 % , Gamimune N 10 % and Thrombate III.

[3] *State Complaint*, ¶¶ 5-10; *Federal Complaint*, ¶¶ 3-8; *Bayer Complaint*, ¶¶ 3-8.

[4] Market reliance upon reported AWPs is discussed in ¶¶ 132-135 of the *State Complaint*; ¶¶ 109-112 of the *Federal Complaint;* and ¶¶ 84-87 of the *Bayer Complaint*.

reported the inflated AWPs to the standard national price compendia (*First DataBank (FDB), Red Book* and *Blue Book*), and the industry based reimbursement amounts on those AWPs. Since providers acquired the drugs at acquisition cost (AC) while payors (Medicare, Medicaid, private Third-Party Payers (TPPs), and consumers) paid for the drugs at reimbursement rates based on the AWPs, the increased "spreads" (AWP – AC) caused by the AWP Scheme increased the profits earned by the providers of the drugs (pharmacies, physicians) at the expense of the payors. The increased profits induced providers to move market share of the relevant drugs, the *raison d'etre* of the AWP Scheme to the drug manufacturers.[5]

4. The relevant Plaintiffs in this matter for whom damages are alleged include, but are not limited to,[6] the following:

a) The State of Nevada

- For pharmaceutical reimbursements under Medicaid
- For pharmaceutical reimbursements under Medicaid for "dual eligibles" under Medicare
- For pharmaceutical reimbursements for State employees
- For pharmaceutical payments made by State agencies

b) Nevada consumers

- Those consumers making drug coinsurance payments under Medicare Part B
- Those consumers making coinsurance payments under a private third-party payer plan
- Those consumers without prescription drug insurance coverage making payments out of pocket

5. The claims for damages and/or financial penalties made by Plaintiffs include, but are not limited to, the following:[7]

a) Restitution for losses incurred by Nevada residents as a result of the AWP Scheme under violation of Deceptive Trade Practices;

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[5] A more complete discussion of the fraud and its market effects are developed in ¶¶ 136-176 of the *State Complaint*; ¶¶ 113-160 of the *Federal Complaint;* and ¶¶ 88-135 of the *Bayer Complaint*.

[6] See ¶¶ 15, 16, 17, 20, 123 and Section X of the *State Complaint*; ¶¶ 11, 12, 13, 16, 100 and Section XI of the *Federal Complaint*; and ¶¶ 11, 12, 13, 16, 75 and Section XI of the *Bayer Complaint*. Since I have not had sufficient time to fully analyze all discovery materials, there may be additional Plaintiff groups and additional drugs subject to damage calculations that I will be able to address, if asked to, in a Supplementary Declaration. I anticipate that those damage calculations will make use of formulaic methods analogous to those put forward here.

[7] See Section XI of the *State Complaint*; Section XII of the *Federal Complaint*; and Section XII of the *Bayer Complaint*. I have been informed by Counsel that the Racketeering claim has been dismissed by the Court.

b) Civil penalties and injunctive relief to prevent harm caused to elderly Nevada residents as a result of the AWP Scheme under violation of Deceptive Trade Practices;

c) Civil penalties, injunctive relief and restitution for losses suffered by the State of Nevada as a result of the AWP Scheme under violation of Deceptive Trade Practices;

d) Civil penalties and recovery of inflated Medicaid reimbursements made by the State of Nevada resulting from fraudulent reporting of inflated AWPs; and

e) Payment of punitive damages to the State of Nevada.

6. To date, Defendants have provided incomplete data and insufficient guidance to fully interpret the data that they have provided to allow me to appropriately calculate damages for all the claims identified above. For example, insufficient data and/or insufficient data description were provided by Defendants to appropriately calculate all damages for all injured parties alleged under the AWP Inflation Scheme. I develop methodologies for calculating damages alleged under the AWP Scheme and use them where the data permits. However, given my inability to fully analyze the data submitted by Defendants, I have been instructed by Counsel to develop alternative methodologies that allow me to calculate aggregate penalties arising from the violations alleged in the Complaint, in the absence of a complete production of data. I reserve the right to supplement my analyses once sufficient data become available. Given the absence of complete information to calculate all damages and penalties for all Plaintiffs injured under the AWP Inflation Scheme, the damages presented in this Declaration are conservative.

7. My Declaration proceeds as follows. In Section II, I conduct the analysis to develop the formulaic methodologies that can be used for calculating the damages and penalties induced by Defendants' conduct. In Section III, I discuss the measurement of specific components of selected formulaic methodologies and the implementation of those methodologies for those groups for which damages and penalties can be calculated. In Section IV, I implement my formulaic methodologies for those drugs, Defendants, and damage/penalty measures for which data are available. Attachment A lists additional materials relied upon and not identified in my declarations previously submitted in this matter.

II. Analysis

A. The Purpose of the Medicaid and Medicare Statutes

8. The Medicaid drug program and the federal and state initiatives to effectuate it have been designed to implement cost-based drug reimbursement. The legislation and regulation enabling the Medicaid drug program have encouraged states to base their payments on Estimated Acquisition Cost (EAC), as reflected in an early Health Care Financing Administration (HCFA) memorandum:

"The intent of the final Medicaid regulations on drug payment is to have each state's estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to see that their ingredient cost levels are as close as possible to actual acquisition cost."[8]

As part of the process, over time states have come to require the amount allowed (AA) for Medicaid reimbursement be **the lesser of** the possible measures of cost – the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the Usual & Customary amount (U&C) charged by a pharmacy, and the amount billed. Which of these alternative prices has been relevant has depended upon whether the drug being reimbursed is a single-source or multi-source drug.

a) For single-source drugs, State Medicaid agencies have focused primarily on determining the EAC (and the dispensing fee for the drug), since EAC is invariably less than U&C and the amount billed. Expecting that the AWP provided a reasonable signal for ASPs and EACs,[9] "[t]he EAC for most States is [has been] calculated by using the average wholesale price (AWP) for the drug less a percentage discount."[10]

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[8] HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: "Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC)." Indeed, in 1976 the Department of Health and Human Services (HHS) implemented drug reimbursement rules articulating upper limits for payments by Medicaid and other programs (45 CFR Part 19). The rules were designed to ensure that the Federal government acts as a cost conscious purchaser of drugs. Of the Federal programs involved, these rules have the greatest impact on the Medicaid program. In 1983, the HHS began reviewing the department's drug reimbursement regulations. The revised regulations were published on July 31, 1987 (52 Fed. Reg. 28648).

[9] Properly measured, the ASP to a particular group of providers is the EAC of that group of providers. I have addressed the equivalence of ASP and EAC in ¶ 10.b) of my September 3, 2004 Declaration in Support of Class Certification in the MDL AWP litigation; in ¶¶ 42, 47 & 49 and footnotes 21 and 75 of my December 16, 2004 Rebuttal Declaration in the MDL litigation; and in Attachment K to my December 15, 2005 Declaration on Liability and Calculation of Damages in the MDL litigation.

[10] See U.S. Department of Health and Human Services, OIG, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002, p. 1. The report continues (p. 1), "The AWP is the price assigned to the drug by its manufacturer and is compiled by the **Red Book, First DataBank, and Medi-Span** for use by the pharmaceutical community. Prior to 1984, most States used 100 percent of AWP for reimbursement of acquisition costs." After 1984, a variety of discounts off AWP were paid by manufacturers, reducing the retailer acquisition cost. These discounts were reflected in the reimbursement amounts allowed. For examples, by 1997 the OIG found that the average discount below AWP to retailers was 18.30% for brand name drugs; by 2002, the OIG found that the average discount below AWP to retailers was 22%. See ¶¶ 21-24 of Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification. This observed discount was reflected in the percentage off AWP incorporated into state Medicaid reimbursement formulae generally.

See also Stephen W. Schondelmeyer and Marian V. Wrobel, "Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices, Final Report," Abt Associates Inc., prepared for Center for Medicare and Medicaid, 2004, p. 4; the National Pharmaceutical Council, "Pharmaceutical Benefits Under State Medical Assistance Programs," 2000, p. 4-51; and Table D.1 of my September 3, 2004 MDL Declaration is Support of Class Certification, which presents each state's Medicaid reimbursement formula relative to AWP as of 2004.

b) For multi-source drugs, FUL and MAC are relevant. Once a sufficient number of generic drugs have launched, Medicaid can reimburse for drugs under the Federal Upper Limit (FUL) program. FUL can be established only if all versions of a drug product have been classified as therapeutically equivalent (A-rated) by the FDA in its publication "Approved Drug Products with Therapeutic Equivalence Evaluations" and at least three suppliers are listed in the current editions of published national compendia. However, FUL is still linked to the AWPs of the related drugs,[11] and this linkage usually limits its ability to constrain price increases.[12]

9. The Medicare Program has limited its drug reimbursement primarily to physician-administered drugs under Part B. Medicare has also been designed to limit the amounts allowed as reimbursement to the costs incurred by providers (physicians) in acquiring the relevant drugs. In Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification, I summarize some history of the Medicare Program and the fact that its original approach to reimbursement was cost-based; see ¶¶ 5-7 of that Attachment D. In footnotes 13-14 to my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages, I present the formulae for reimbursement rates under Medicare for physician-administered drugs over time. The criteria consistently involve the lesser of the acquisition cost of the physician and AWP less some amount.

10. Hence, Nevada's procedures for reimbursement of drug-related claims under Medicaid and Medicare have been designed to guarantee that the amount allowed as reimbursement approximates as nearly as possible the acquisition costs incurred by the providers of those drugs.

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[11] For example, under 42 CFR 447.332 (b), the FUL price is required to be set at an amount equal to 150 percent of the published price (in *Blue Book*, *Medi-Span* and/or the *Red Book*) for the least costly generic substitute (as purchased by pharmacists in quantities of 100 units (tablets or capsules)). There seems to be conflicting information as to whether FUL is set at 150% of the lowest AWP or at 150% of other prices that are published in national compendia. For example, one OIG report states that it is set off of AWP: "The upper limit amounts are based on 150 percent of AWP for the lowest priced generic equivalent." See *Medicaid Pharmacy – Actual Acquisition Costs of Generic Prescription Drug Products*, Office of Inspector General, Department of Health and Human Services, March 2002, A-06-01-00053 at p. 4. However, in a CMS response by Mark McClellan to another OIG report (*How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List*, Office of Inspector General, Department of Health and Human Services, September 2005, OEI-03-05-00350), he states: "Federal regulation (42 CFR Section 447.332) requires the FUL amount to be 150 percent of the published price for the least costly therapeutic equivalent using data from all available national compendia. The FUL system selects the lowest price of average wholesale price (AWP), wholesale acquisition cost (WAC), or direct price (DP), as reported by the national compendia, to arrive at the FUL price" (at p. 13). Invariably, however, EAC is less than 150% of any of these list prices.

[12] According to Table D.1 of Attachment D to my September 3, 2004 Declaration in Support of Class Certification, Nevada does not have a State MAC. I understand however that Nevada implemented a State MAC on December 17, 2003, the details of which are proprietary and implemented by First Health Services. (See Letter to Pharmacy Providers, from Charles Duarte, Administrator, Division of Health Care Financing and Policy, State of Nevada, dated December 16, 2003 as accessed at https://nevada.fhsc.com/Downloads/provider/MAC_introduction.pdf) Since the State MAC was implemented after the period of time for which we have data, it does not enter into my calculations. However, my formulaic methodologies would be unchanged even if a State MAC had existed and had been used.

B. Implications of the AWP Inflation Scheme for Drugs Reimbursed Under Medicaid and Medicare

11. To the extent that the alleged AWP Scheme was effectuated by Defendants, the Scheme would have revealed itself in an "excessively" large spread or deviation between an inflated AWP and the acquisition cost of (or sale price to) the relevant providers, for which the AWP is generally taken as a signal.[13] This inflation affected all purchasers of the relevant pharmaceuticals. However, I focus here on the effects of reimbursement under Medicaid and Medicare.

12. As noted in the *Complaints* (*State Complaint*, at ¶ 133; *Federal Complaint*, at ¶ 110; *Bayer Complaint* at ¶ 85), the Office of the Inspector General (OIG) of the Department of Health and Human Services (DHHS) affirms that the "government sets reimbursement with the expectation that the data provided are complete and accurate." Specifically,

> "Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using prices and sales data directly or indirectly furnished by pharmaceutical manufacturers. The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable. …
>
> Where appropriate, manufacturers' reported prices [therefore] should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products. … Underlying assumptions used in connection with reported price should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements."[14]

13. Defendants are alleged to have distorted the pricing information upon which government programs rely, with the specific intention of artificially inflating spreads.[15]

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[13] Methods for calculating overcharge damages induced by the "AWP Inflation Scheme" have been identified and implemented previously in the MDL AWP matter and in the Connecticut AWP matter. See the Declaration of Raymond S. Hartman in Support of Class Certification, September 3, 2004 and the Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005, both *In re Pharmaceutical Industry Average Wholesaler Price Litigation*; and Calculation of Damages to Connecticut for State Expenditures under the Medical Assistance Programs, Declaration of Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, January 19, 2006 and Expert Disclosure, Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, November 1, 2005.

[14] US DHHS, OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers*, April, 2003. pp. 11-12; cited in *State Complaint*, at ¶ 133; *Federal Complaint*, at ¶ 110; *Bayer Complaint* at ¶ 85.

[15] *Ibid*., pp. 26-27; cited in *State Complaint*, at ¶ 134; *Federal Complaint*, at ¶ 111; *Bayer Complaint* at ¶ 86.

> "The 'spread' is the difference between the amount a customer pays for a product and the amount the customer receives upon resale of the product to the patient or other payer. In many situations under the federal programs, pharmaceutical manufacturers control not only the amount at which they sell a product to their customers, but also the amount those customers who purchase the product for their own accounts and thereafter bill the federal health care programs will be reimbursed. To the extent that a manufacturer controls the 'spread', it controls its customer's profit.
>
> Average Wholesale Price (AWP) is the benchmark often used to set reimbursement for prescription drugs under the Medicare Part B program. For covered drugs and biologicals, Medicare Part B generally reimburses at '95 percent of average wholesale price.' ...Similarly many state Medicaid programs and other payers base reimbursement for drugs and biologicals on AWP. Generally, AWP or pricing information used by commercial price reporting services to determine AWP is reported by pharmaceutical manufacturers.
>
> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customers from a subsequent purchaser (the federal or state government). Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread' to induce customers to purchase its product."

14. For purposes of this discussion, I use ASP to denote the average sales price to the relevant class of trade (e.g., retail pharmacies, physicians), which is equivalent to the acquisition cost (AC) of that class of trade when properly measured (see footnote 9 above). While the "spread" is often measured using the AWP and the ASP,[16] it can also be measured as the "spread" or difference between the reimbursement rates that are related to the AWPs and the ASPs which measure provider acquisition costs.

For purposes of this analysis, I make use of the latter definition of spread. I focus upon the spreads between the amounts allowed to providers as drug reimbursement under the Medicaid and Medicare Programs relative to costs at which those providers acquire those drugs. I have been advised by Counsel that if these spreads are larger than allowed by the relevant statute(s), the AWP Scheme led to excessive reimbursement for drug claims. I can calculate the overcharge damages arising from that artificial AWP inflation. I can also determine whether the amounts allowed as reimbursement constitute an excessive amount deceptively charged to and/or falsely claimed in Medicaid and Medicare reimbursement claims.

[16] For example, it can be expressed as (AWP – ASP)/ASP, (AWP – ASP)/AWP, AWP/ASP, or (AWP – ASP). I have addressed these other formulations in my earlier MDL analyses before this Court and in my Connecticut analysis.

C. Calculation of Overcharge Damages Under Medicaid and Medicare Arising from the AWP Inflation Scheme

15. Under Medicaid and Medicare, the amount allowed (AA) as reimbursement is related formulaically to the actual (and allegedly artificially inflated) AWP.[17] Specifically, for a given claim, AA = "AWP – x%" + df[18] = (100% – x%)*AWP + df = p*AWP + df for any x%,[19] where the dispensing fee is designated as df and where p = (100 – x)%.[20] Denote the but-for allowed amount as $AA^{but\text{-}for}$.[21] The difference between AA and $AA^{but\text{-}for}$ can be used to calculate overcharge damages as follows.

16. For each year of the period alleged to be subject to the AWP Inflation Scheme, State claims data summarize total number of claims and total dollar reimbursements paid by the State under the Medicaid Program and for drugs reimbursed for dual-eligibles (payment of Medicare supplemental insurance amounts (20%) for physician-administered drugs) by NDC and/or by J-Code.[22] For a given NDC or J-Code, those data would reflect the following:

(1a) Actual Reimbursements = $\Sigma_i AA_i * q_i = \Sigma_i (p*AWP + df)_i * q_i = (p*AWP + df)*Q$,

where Actual Reimbursements is the total dollar amount of claims paid in a given year; Σ_i is the summation of the allowed amount$_i$ (AA_i) times the number (q_i = quantity$_i$) of claims (alternatively the units reimbursed per claim) reimbursed at AA_i; and Q is the total claims or total units reimbursed by the State at an average allowed amount of AA^{avg} = (p*AWP + df).[23]

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[17] As discussed below, the methodology accommodates the reliance upon FUL, U&C or amount billed when they are the basis for AA in the claims data.

[18] Note that I use industry nomenclature to designate reimbursement off AWP as "AWP less some percent (x%)", which really means (100% - x%)*AWP.

[19] According to CMS materials dated June 2004, the reimbursement formulation for self-administered drugs in Nevada is AWP – 15% under Medicaid, for both branded and generic drugs; the dispensing fee (df) is $4.76; and Nevada has no MAC (see Table D-1, Attachment D to my September 3, 2004 MDL Declaration in Support of the Certification of Class). While information presented in footnote 12 clarifies the status of the State MAC, this information has no impact upon my analysis and calculations. From 1991 through June 2002, I understand that the reimbursement formula was AWP – 10% and AWP – 15% beginning in July 2002.

The amount allowed under Medicare is AWP – x%, where x% is designated over time as delineated in footnote 13 to my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages.

[20] Of course, in the actual calculations the percentages are denoted as follows: 100% = 1.00; 15% = 0.15; 10% = 0.10; etc.

[21] Which would be related to a but-for non-inflated AWP as $AA^{but\text{-}for} = AWP^{but\text{-}for} - x\% + df = (100\% - x\%)*AWP^{but\text{-}for} + df = p*AWP^{but\text{-}for} + df$.

[22] To date, I have received State data only for reinbursement of drug claims under Medicaid for 1991 through 2002. I have not received any data for reimbursement for physician-administered drugs under J-codes.

[23] The State data summarize reimbursement for all claims. Hence, if some claims are determined by FUL, U&C or the amount billed (all of which I understand are related to AWP) or the proprietary MAC of First Health Services, the AA for those claims are specific to that definition and AA^{avg} reflects those claims.

Had these reimbursements been made at the but-for allowed amount per claim i ($AA^{but\text{-}for}{}_i$), the total reimbursements that should have been paid by the State in a given year would have been,

(1b) But-For Reimbursements = $\Sigma_i AA^{but\text{-}for}{}_i * q_i = (AA^{but\text{-}for\text{-}avg}) * Q$,

where the total number of units is assumed to be the same in the but-for and actual worlds.

Having calculated But-For Reimbursements, the damages to the State for reimbursements for drug j of Defendant k are

(1c) Overcharge $Damages_{jk}$ = Actual $Reimbursements_{jk}$ – But-For $Reimbursements_{jk}$

$$= \Sigma_i AA_i * q_i - \Sigma_i AA^{but\text{-}for}{}_i * q_i$$

$$= (AA^{avg} - AA^{but\text{-}for\text{-}avg})Q.$$[24]

17. Aggregate overcharge damages (1c) can be calculated for all units of drug j sold by Manufacturer k and reimbursed by the State as a whole for the Damage Period as a whole; alternatively, it can be calculated for some subset of NDCs of drug j for some subset of State reimbursements for some sub-period of the Damage Period. The use of Equation (1c) is particularly straightforward. The State has data for Actual $Reimbursements_{jk}$ for all relevant drugs and Defendant manufacturers, for the relevant Damage Period, for Medicaid and Medicare program reimbursements. The But-For Reimbursements are determined by statute.

D. Calculation of Penalties for Deceptive Practices and False Claims Under the AWP Inflation Scheme

18. Under Counts I and II of the *Complaints*, the claim is made for restitution of losses suffered by residents of the State of Nevada as a result of the AWP Scheme. Count II also brings a claim for civil penalties of $10,000 per violation when that violation involves an elderly resident.

19. Under Count III of the *Complaints*, the claim is made for restitution of losses suffered by the State of Nevada as a result of the AWP Scheme. I understand that Defendants conduct as alleged constitutes deceptive acts or practices in violation of Nevada code for the following transactions: those in which the AWP was inflated; those for which Defendant manufacturers failed to disclose material facts that the AWP exceeded the average of the wholesale price based upon a good faith and reasonable estimate; and/or those in which the Defendant manufacturers knowingly made false representations by representing that the AWP was an accurate reflection of the average wholesale price. Pursuant to NRS 598.0999, the *Complaints* state that the Court can assess civil penalties of $2,500 from each Defendant for each willful violation of NRS 598.0903 to 598.0997.

[24] And if we make use of a but-for non-inflated AWP, Overcharge $Damages_{jk}$ = $(p*AWP + df)*Q - (p*AWP^{but\text{-}for} + df)*Q$.

20. Under Count V of the *Complaints*, the claim is made for recovery of treble damages and civil penalties. Accordingly, if liable, each Defendant will be assessed an amount equal to three times the amount unlawfully obtained and pay civil penalties of not less than $5,000 for each false claim, statement or representation.

21. I have been directed by Counsel to assume that penalties of $7,500 (i.e., $2,500 plus $5,000) can be assessed for each claim submitted for reimbursement under Medicaid and Medicare that was subject to a deceptive practice and was false.[25] The number of such claims can be calculated as follows.

22. As noted in ¶ 8 above, the allowed amount (AA) under Medicaid is to be the lesser of {the EAC, the Federal Upper Limit (FUL), the state maximum allowable cost (MAC), the Usual & Customary amount (U&C) charged by a pharmacy, or the amount billed}. Likewise, as noted in ¶ 7 above, EAC is invariably the lowest price.

Hence, for any drug reimbursed under Medicaid, I have been instructed by Counsel that liability occurs as a matter of law if $AA_{jk} > EAC_{jk}$. Furthermore, as discussed above (see footnote 9), $EAC_{jk} = ASP_{jk}$ to the relevant group of providers (pharmacies, physicians). For self-administered drugs reimbursed under Medicaid, j denotes the NDC of the drug and k denotes the Defendant. For physician-administered drugs, j denotes the NDC or the J-Code and k denotes the Defendant.

23. I have been provided with information from the State sufficient to calculate AA_{jk} by claim. While I received from Defendants a variety of data sets summarizing (to varying degrees of completeness) invoice information, rebates information and other accounting information, I have not received from Defendants sufficient explanation and clarification of these data to accurately calculate the ASP_{jk} by NDC and/or J-Code for most drugs and most Defendants in this matter. Indeed, the data that I have been able to use to analyze liability using ASPs have been developed as part of the MDL AWP litigation addressing the Track 1 Defendants and the Connecticut AWP litigation.

Given this limited ability to make use of discovery materials, I have developed a method to make use of the existing information to draw conclusions regarding liability. Specifically,

a) For claims for reimbursement for single-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.

[25] As currently implemented, my methodology focuses upon accurately calculating the total number of claims that were deceptive and false. However, it is possible that I can identify those claims submitted by elderly residents. If I were able to distinguish those claims submitted by elderly residents, I understand that an additional penalty of $10,000 per claim could be imposed. Should I be asked to do so, I could submit such calculations in a supplemental analysis. Should I receive any supplementary direction from the Court regarding the amount of the penalty to be assessed per false and deceptive claim, the calculation of aggregate penalties will be very easy to revise to accommodate those alternative directions. The revised calculation is simple arithmetic.

- Since the Amount Billed and the U&C > EAC, EAC will be the lesser of the alternative reimbursement bases.[26]
- AWP – (16.6%-20%)[27] = WAC
- I understand that the retail acquisition costs (RAC) is approximately equal to WAC and indeed may be slightly less {that is, RAC (EAC) < WAC}, perhaps 1-2% of AWP.[28] To be conservative, I assume that RAC = EAC ≈ WAC.[29]
- Using the upper bound of these discounts off AWP, if AA > AWP – 20%, AA exceeds EAC.
- Using the lower bound of these discounts off AWP, AA > AWP – 16.6%, AA exceeds EAC.
- Absent a measure of ASP, I let the threshold for liability be AA > AWP – 20%. For sensitivity analysis, I let the threshold for liability be AA > AWP – 16.6%. In each case, if AA exceeds the threshold I conclude AA fraudulently exceeds EAC.

b) For claims for reimbursement for multi-source self-administered drugs, I conclude liability as follows:

- For those NDCs for which I have ASPs and for which AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC.
- Since the Amount Billed and the U&C > EAC; since FUL > EAC; and since Nevada did not have a State MAC during the period for which I have data; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that EACs (i.e., ASPs or RACs) < AWP – (16.6%-66%)[30] over the period 1991-2002.
- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a reasonable threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, in my calculations in Section IV below, I bound this reasonable threshold by allowing the threshold to be AWP – 20% and AWP – 66%.

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[26] The U&C is the "walk-in" price paid by uninsured cash payers; it is usually ≈ AWP.

[27] These discounts off AWP are equivalent to spreads of 20%-25% above WAC. For example, if AWP – 20% = WAC; then AWP (100%-20%) = .80*AWP = WAC; and AWP = 1.25 WAC or WAC + 25%.

[28] See footnote 10 above.

[29] This understanding is corroborated by Defendants' Experts; see footnote 9 above.

[30] Since evidence indicates that EAC < 16.6%-20% for brand name drugs, it is well known that the discount off AWP for generic drugs will be greater than 16.6% - 20%. For example, by 1997, the OIG found that the average discounts below AWP at retail were 42.45% for generics. By 2002, OIG found these discounts from AWP to be even deeper, approximately 66%. See ¶¶ 21-24 of Attachment D to my September 3, 2004 MDL Declaration in Support of Class Certification. Both of these OIG reports used a sampling of states. The earlier report used a sample of ten states and the District of Columbia; the later report used a sample of 8 states. See *Medicaid Pharmacy – Actual Acquisition Costs of Generic Prescription Drug Products*, Office of Inspector General, Department of Health and Human Services, March 2002, A-06-01-00053.

c) For claims for physician-administered drugs reimbursed under Medicaid, I conclude the following:

- For those drugs for which I have ASPs and AA > ASP = EAC, I conclude that AA fraudulently exceeds EAC. The ASP may be delineated by NDC or J-Code. Given the time consuming process of performing the cross-walk for multi-source physician-administered drugs reimbursed by J-Code, I would not analyze liability for physician-administered drugs once they go generic, even if I had ASP data for a generic drug of a Defendant. This concern was not relevant for physician-administered drugs reimbursed by J-Code, because such data was not made available by Nevada.
- Since the Amount Billed, the U&C and FUL > EAC; and since Nevada did not have a State MAC until December 2003; EAC will be the lesser of the alternative reimbursement bases.
- Evidence demonstrates that for single-source drugs, physician acquisition cost (PAC) is at most equal to WAC and often much less (i.e., PAC < AWP – (20%-75%).
- Absent a measure of ASP, and given the fact that I have not made a complete enough analysis of the pattern of increasing discounts off AWP over the Damage Period, I conclude that a conservative threshold for liability for the Damage Period as a whole is AA > AWP – 25%. If AA exceeds this threshold, I conclude AA fraudulently exceeds EAC.
- However, in my calculations in Section IV, I bound this threshold by allowing the threshold to be AWP – 20% and AWP – 66%.
- The State of Nevada was unable to provide data relating to physician-administered drugs reimbursed by Medicaid and reported by J-Code. Consequently, I do not implement this methodology and I do not report any damages or penalties for this segment of drugs, if reported by J-Code. This exclusion makes my calculation of penalties conservative.

24. For the analysis of Medicaid reimbursement for dual-eligible Medicare claims, State medical claims normally summarize reimbursement for the 20% Medicare coinsurance by J-Code. While penalties for reimbursement of such claims would be analyzed as in ¶ 23.c) above, the claims and reimbursement data could not be provided by Nevada. Should such data be made available I will implement a methodology by J-Code similar to that described in ¶ 23.c) above. This exclusion makes my calculation of penalties conservative.

III. Selected Issues Arising with Implementation of the Formulaic Methodology for Damage Calculation

A. Reimbursement for Drug Claims Under Nevada's Medicaid Program

25. The reliance of Nevada's Medicaid Program upon AWP for reimbursement resembles Medicaid reimbursement in most states.[31] Specifically, the *Complaints* state

> "Medicaid payments for outpatient drugs include two components: acquisition costs and dispensing fees. The Nevada Medicaid program presently reimburses for outpatient drugs on the basis AWP less 15% plus a $4.76 dispensing fee. ... For generic drugs for which Federal Upper Limits ("FUL") have been set by HCFA, the reimbursement amount is the FUL plus a $4.76 dispensing fee. ... The Nevada Medicaid Program uses the AWP as reported by *First DataBank*."[32]

26. However, the EAC is consistently less than U&C (the "walk-in" price charged to uninsured cash payers, which is usually ≈ AWP), FUL (which is 150%* the lowest AWP or WAC) and AWP – x% (10% or 15%). Thus, while legislation and regulation of the Medicaid drug program has encouraged states to base their payments on Estimated Acquisition Cost (EAC = ASP), state Medicaid programs have not. Instead, they have been forced to base their reimbursements on AWP.[33] As a result, Defendant Manufacturers' AWP Scheme and reliance by the State upon AWP has caused the State of Nevada to be overcharged as follows.

Using the notation of ¶¶ 15-16 above

a) For self-administered drugs through June 2002 $AA = AWP - 10\% + df = 0.90*AWP + df$, and $AA^{but\text{-}for} = EAC + df = ASP + df$.

b) For self-administered drugs after June 2002 $AA = AWP - 15\% + df = (100\% - 15\%)*AWP + df = 0.85*AWP + df$, and $AA^{but\text{-}for} = EAC + df = ASP + df$.

c) I have been informed by Counsel that the reimbursement formula switched from AWP - 10% to AWP - 15% on July 1, 2002.[34]

d) For physician-administered drugs reimbursed by Nevada as a drug claim (and therefore reported by NDC), I assume the same reimbursement formulae.

27. While Nevada statutes indicate that the amount allowed on all, or at least substantially all, drug claims is formulaically based on AWP in this fashion, the actual calculation of AA_i, $\Sigma_i AA_i$ and AA^{avg} in Section IV below is based upon the claims themselves. Actual claim amounts are compared with actual ASPs, when those ASPs are available.

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[31] See Attachment D generally and Table D-1 specifically of my September 3, 2004 Declaration in Support of Class Certification in this matter.

[32] See *State Complaint* ¶ 126; *Federal Complaint* ¶ 103; *Bayer Complaint* ¶78. Note, however, that the *State Complaint* indicates that the current reimbursement is based on AWP-10%. It is my understanding that the allowed amount changed to AWP-15% effective July 1, 2002. The other two complaints cite AWP-15%.

[33] See ¶ 8 and footnote 10 above.

[34] The change to AWP-15% effective July 1, 2002, has been confirmed by the State of Nevada.

28. When ASPs have not been available and I have relied upon the thresholds determined as in ¶ 23 above, I also rely upon claims data and the thresholds calculated relative to AWPs.

B. Reimbursement for Drugs Reported as Medical Claims Under Nevada's Medicaid Program

29. Medicaid reimburses for physician-administered drugs recorded as Medical claims using J-Codes for two groups of patients: i) those patients strictly covered by Medicaid, and ii) those patients covered by Medicare whose 20% co-insurance is covered by Medicaid ("dual eligibles"). Reimbursement formulae and calculation issues for the first set of medically-related drug claims are the same as those discussed above in ¶¶ 25-28 for Medicaid drug claims. Reimbursement formulae and calculation issues for the second set of medically-related drug claims (dual eligibles) are determined by the Medicare reimbursement formulae presented in footnote 13 of my December 15, 2005 MDL Declaration on Liability and the Calculation of Damages.

30. However, I have received no data from the State of Nevada summarizing physician-administered drug claim reimbursements reported by J-Code. As a result, I do not calculate damages or penalties for this group of claims. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

C. Reimbursement for Drug Claims and Medical Claims For State Employees and State Agencies

31. The drugs for which reimbursement was paid based upon AWP by these groups will likewise be categorized as self-administered branded drugs, self-administered generic drugs or physician-administered drugs. Calculation of overcharge damages and the penalties for false and deceptive claims would proceed as above, if I had been provided with claims data for these groups. I was not, and do not therefore calculate overcharge damages or identify the number of false and deceptive claims subject to recovery of penalties. Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

D. Reimbursement for Drug Payments Made by Uninsured Consumers

32. The price of drugs to walk-in customers without insurance is understood to be U&C ≈ AWP. Such consumers have been overcharged by the AWP Scheme. I have no data summarizing these reimbursements; hence, I cannot calculate the related damages or penalties. Indeed, I have been provided with no data with which to calculate overcharge damages and/or penalties for deceptive practices for the residents of Nevada due to the AWP Scheme, including elderly residents (Count II, discussed in ¶ 18 above). Hence, my calculation of aggregate overcharge damages and my measures of penalties for false and deceptive claims are conservative.

E. Analysis of Medicaid Rebates

33. I have not received data on Medicaid rebates paid to the State. According to the CMS Medicaid Drug Rebate Program, Medicaid rebates are to be calculated as a fixed percentage of AMP ("Average Manufacturer Price"),[35] which purports to approximate the ASP. For the purposes of the overcharge damage analysis, I assume that AMP is the same in the actual and but-for worlds (since ASP is the same), and therefore the total amount of rebates received by the state is the same in the actual and but-for worlds. As a result, if properly paid in the actual world, Medicaid rebates net out of the damage calculation.[36] However, if rebates were not paid in the actual world, overcharge damages incurred by the State are higher than those calculated here.[37]

IV. The Calculation of Damages and Recovery of Penalties for False Claims and Deceptive Practices

34. Tables 1-3 summarize the calculations of overcharge damages and the measures of recovery for false claims and deceptive practices, making use of the methodologies presented above.[38]

a) Table 1 presents selected overcharge damages by Defendant and by Drug, for each of the *Complaints*, when the reimbursement claims provided by Nevada are drug claims reported by NDCs. Recall that almost no information was available to me to calculate aggregate overcharge damages. As a result, the sum of overcharge damages in Table 1 is useful for illustration rather than as a basis for recovery for economic injury.

b) Table 2 summarizes my analysis of claims data for single-source self-administered drugs. It presents information regarding the total number of claims for such drugs by Defendant for each of the *Complaints*; it tabulates those claims

[35] See http://www.cms.hhs.gov/MedicaidDrugRebateProgram; rebates for innovator drugs are set at 15.1% of AMP; and rebates for non-innovator drugs are set at 11% of AMP.

[36] State reimbursements for Medicaid should net out rebate payments. Specifically, Actual Net Reimbursements = Actual Reimbursements – Actual Rebates. Likewise, But-For Net Reimbursements = But-For Reimbursements – But-For Rebates. Therefore, Overcharge Damages = Actual Net Reimbursements – But-For Reimbursements = (Actual Reimbursements – Actual Rebates) – (But-For Reimbursements – But-For Rebates). However, since ASP and AMP are the same in both the but-for and actual worlds, Actual Rebates = But-For Rebates, and Overcharge Damages = Actual Reimbursements – But-For Reimbursements (as in Equation (1c)).

[37] Using the notation in the preceding footnote, Overcharge Damages = Actual Net Reimbursements – But-For Reimbursements = (Actual Reimbursements – Actual Rebates) – (But-For Reimbursements – But-For Rebates). When rebates are paid in the actual world and by reasonable assumption are the same in the but-for world, the rebates net out of the damage calculation, as above. If however, Actual Rebates = $0 when Actual Rebates should = But-For Rebates > 0, then Corrected Overcharge Damages = (Actual Reimbursements – 0.00) – (But-For Reimbursements – But-For Rebates) = (Actual Reimbursements – But-For Reimbursements) + **But-For Rebates** > my calculated Overcharge Damages = Actual Reimbursements – But-For Reimbursements.

[38] Note that none of these calculations take account of pre-judgment interest. They are therefore conservative.

that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASPs and those identified on the basis of the threshold amounts related to the drugs' AWP. I have allowed for two thresholds: AA > AWP – 16.6% and AA > AWP – 20%. If AA exceeds the ASP or the threshold, I conclude AA fraudulently exceeds EAC.

c) Table 3 summarizes my analysis of claims data for multi-source self-administered drugs. It presents information regarding the total number of claims for such drugs by Defendant for each of the *Complaints*; it tabulates those claims that can be identified as false or deceptive by comparison of the claimed amount (AA) with drugs' ASPs and those identified on the basis of the threshold amounts related to the drugs' AWP. While I conclude that the threshold of AWP – 25% is reasonable for the Damage Period as a whole, I bound this threshold by allowing the liability threshold to be AWP – 20% and AWP – 66%.

35. To summarize the results of these Tables, I find (and where appropriate report in Table 4):

a) Given the paucity of data I can effectively use to calculate actual ASPs, I am able to calculate overcharge damages for a *de minimis* number of drugs designated by NDC. The measure of aggregate overcharge damages for both sets of drugs found in Table 1 is $1.3 million.

b) The number of claims that are false and subject to deceptive practices is substantial under widely different bounds for reasonable thresholds of calculating the EAC relative to the reported AWP.

- In Table 2, the total number of such claims for single-source self-administered drugs ranges from 5 (for Watson) to 392,881 (for Pfizer) across Defendants. Since the penalty for such deceptive and false practices is $7,500 in total, the amount of the recovery for that penalty is also substantial, ranging from $37,500 (for Watson) to $2.9 billion (for Pfizer) across Defendants. The total recovery for this class of drugs for this Period is approximately $11.0 billion.

- In Table 3, the total number of such claims for multi-source self-administered drugs ranges from 2 (for Fujisawa Group) to 90,670 (for Schering-Plough) across Defendants. Again, since the penalty for such deceptive and false practices is $7,500 in total, the amount of the recovery for that penalty is also substantial, ranging from $15,000 (for Fujisawa Group) to $680 million (for Schering-Plough) across Defendants. The total recovery for this class of drugs for this Period ranges from $957 million to $1.2 billion, depending on the threshold.

- In Table 4, the range of penalties based upon the bounds of the thresholds is $11.9 billion to $12.2 billion.

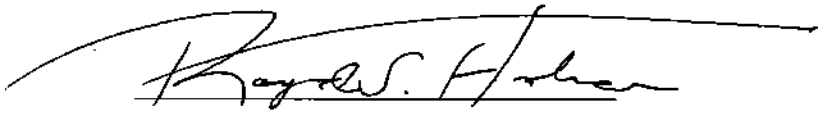
36. While the assumptions regarding thresholds for EAC in Tables 2 and 3 are reasonable, they are assumptions. In Table 5, I present supplemental calculations for the number of false and deceptive claims making no assumption regarding EAC. Instead, I count the number of claims for each type of drug (single-source self-administered, multi-source self-administered and physician-administered) the allowed amount for which

exceeds that amount allowed under the Medicaid statute; i.e., AA > AWP – 10% and AA > AWP – 15% for the relevant periods of time (see ¶¶ 25-26 above). Note that I conduct this analysis only for the claims for which I do not have ASPs and therefore have made assumptions about the thresholds for EAC. For those drugs for which I have ASPs, I can relate AA to the EAC = ASP.

For those drugs for which I can calculate ASPs, Table 5 indicates that the allowed amount exceeds the ASP on 8,464 claims for single-source drugs and 78,510 claims for multi-source drugs. Using the statutory reimbursement amounts for those drugs for which I do not have ASPs, I find that the amount allowed exceeds the statutory reimbursement allowance on 1.4 million claims for single-source drugs and on 40,223 claims for multi-source drugs. For all claims identified as false and deceptive in Table 5, I find that total penalties are $11.4 billion across Defendants.

37. These results are based upon Nevada Medicaid claims data which I had been informed were net of the dispensing fee related to each claim. I have been informed several hours before filing this Declaration that the Nevada Medicaid claims data are not net of the related dispensing fee. At this stage of the analysis, it is impossible to both corroborate this new information and, if corroborated, incorporate the information into my conclusions. I will provide and summarize corrected versions of Tables 1-5 in a supplementary report, once this issue has been resolved.

I declare that this declaration is true and correct.



June 13, 2006

Attachment A

Additional Materials Relied Upon

CMS, CMS response by Mark McClellan to another OIG report (*How Inflated Published Prices Affect Drugs Considered for the Federal Upper Limit List*, Office of Inspector General, Department of Health and Human Services, September 2005, OEI-03-05-00350)

Deposition of Ronald Swenson, January 5, 2006, *In re Pharmaceutical Industry Average Wholesale Price Litigation*; MDL Docket No. Civil Action, 01CV12257-PBS.

Hartman, Raymond, Declaration of Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, January 19, 2006 and Expert Disclosure, Raymond S. Hartman, *State of Connecticut v. Dey, Inc., et al.*, November 1, 2005

State of Nevada, State of Nevada's Amended Complaint, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, United States District Court for the District of Massachusetts, August 1, 2003

State of Nevada, State of Nevada's First Amended Complaint, *State of Nevada v. Abbott Laboratories, et. al.* Case No. CV 02-00260; Dept. No. 8, In the Second Judicial District Court in and for the County of Washoe, State of Nevada, October 31, 2003

State of Nevada, State of Nevada's Amended Complaint Against Defendant Bayer Corporation, *State of Nevada v. Bayer Corporation*, No. CV 02-00260, Dept. No. 8, In the Second Judicial District Court in and for the County of Washoe, State of Nevada, February 27, 2004

State of Nevada, Letter to Pharmacy Providers, from Charles Duarte, Administrator, Division of Health Care Financing and Policy, State of Nevada, dated December 16, 2003 as accessed at https://nevada.fhsc.com/Downloads/provider/MAC_introduction.pdf

Table 1: Calculation of Overcharge Damages for Selected Drugs Reimbursed Based on NDCs

State Complaint

Defendant	Drug	Total by Drug
AstraZeneca	PULMICORT	5,868
	ZOLADEX	5,376
AstraZeneca Total		**$11,245**
Aventis	ANZEMET	4,092
	TAXOTERE	
Aventis Total		**$4,092**
Johnson & Johnson Group	PROCRIT	37,783
	REMICADE	0
Johnson & Johnson Group Total		**$37,783**
Schering-Plough Group	INTRON A	6,189
	PERPHENAZINE	6,098
	PROVENTIL	31,510
	TEMODAR	13,954
Warrick Pharmaceuticals	ALBUTEROL	1,223,664
Schering-Plough Group Total		**$1,281,415**
Total Overcharges for State Complaint		**$1,334,535**

Federal Complaint

BMS Group	BLENOXANE	
	CYTOXAN	4,078
	PARAPLATIN	
	TAXOL	
	VEPESID	5,057
BMS Group Total		**$9,134**
Pharmacia	ADRIAMYCIN	0
	AMPHOCIN	559
	NEOSAR	0
Pharmacia Total		**$559**
Total Overcharges for Federal Complaint		**$9,693**
Total Overcharges for State and Federal Complaint (Combined)		**$1,344,228**

Table 2: Deceptive Trade and False Claims Penalties - Single-Source Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds*[1]			*Penalties (ASP and (AWP - 16.6%))*			*Penalties (ASP and (AWP - 20.0%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshhold Analysis	# of Fraudulent Claims Based on (AWP-16.6%)	# of Fraudulent Claims Based on (AWP-20.0%)	Deceptive Trade ($2500/claim)	False Claim ($5000/claim)	Total Penalties	Deceptive Trade ($2500/claim)	False Claim ($5000/claim)	Total Penalties
State Complaint												
Amgen	2,849	0	0	2,849	2,457	2,556	$6,142,500	$12,285,000	$18,427,500	$6,390,000	$12,780,000	$19,170,000
AstraZeneca	141,150	4,129	3,627	137,021	131,887	132,311	$338,765,000	$677,570,000	$1,016,355,000	$339,645,000	$679,690,000	$1,019,535,000
Aventis Group	82,002	12	12	81,990	77,467	77,767	$193,772,500	$387,545,000	$581,317,500	$194,447,500	$388,895,000	$583,342,500
Boehringer Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Braun	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Fujisawa Group	579	0	0	579	452	465	$1,130,000	$2,260,000	$3,390,000	$1,162,500	$2,325,000	$3,487,500
Immunex	157	0	0	157	39	39	$97,500	$195,000	$292,500	$97,500	$195,000	$292,500
Johnson & Johnson	270,923	483	396	270,440	248,983	251,680	$623,447,500	$1,246,895,000	$1,870,342,500	$630,190,000	$1,260,380,000	$1,890,570,000
Novartis	145,428	0	0	145,428	132,030	132,548	$330,075,000	$660,150,000	$990,225,000	$331,370,000	$662,740,000	$994,110,000
Pfizer	419,816	0	0	419,816	391,400	392,881	$978,500,000	$1,957,000,000	$2,935,500,000	$982,202,500	$1,964,405,000	$2,946,607,500
Schering-Plough Group	136,550	4,216	4,001	132,334	125,357	125,721	$320,395,000	$646,790,000	$970,185,000	$324,305,000	$648,610,000	$972,915,000
Sicor Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Watson	5	0	0	5	5	5	$12,500	$25,000	$37,500	$12,500	$25,000	$37,500
Total State Complaint	1,199,459	8,840	8,036	1,190,619	1,110,107	1,115,973	$2,795,357,500	$5,590,715,000	$8,386,072,500	$2,810,022,500	$5,620,045,000	$8,430,067,500
Federal Complaint												
Abbott	17,801	0	0	17,801	14,928	15,075	$37,320,000	$74,640,000	$111,960,000	$37,687,500	$75,375,000	$113,062,500
Baxter	591	0	0	591	99	99	$247,500	$495,000	$742,500	$247,500	$495,000	$742,500
BMS Group	213,867	462	428	213,405	197,833	198,904	$495,832,500	$991,305,000	$1,487,137,500	$498,330,000	$996,660,000	$1,494,990,000
Dey	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Pharmacia Group	51,543	0	0	51,543	48,199	49,256	$122,997,500	$245,995,000	$368,992,500	$123,140,000	$246,280,000	$369,420,000
TAP	34,847	0	0	34,847	33,288	33,310	$83,220,000	$166,440,000	$249,660,000	$83,275,000	$166,550,000	$249,825,000
Total Federal Complaint	318,669	462	428	318,187	295,347	296,644	$739,437,500	$1,478,875,000	$2,218,312,500	$742,680,000	$1,485,360,000	$2,228,040,000
Bayer Complaint												
Bayer	41,162	0	0	41,162	39,872	39,923	$99,680,000	$199,360,000	$299,040,000	$99,807,500	$199,615,000	$299,422,500
Total Bayer Complaint	41,162	0	0	41,162	39,872	39,923	$99,680,000	$199,360,000	$299,040,000	$99,807,500	$199,615,000	$299,422,500
Total-All Defendants	1,559,290	9,322	8,464	1,549,968	1,445,326	1,452,540	$3,634,475,000	$7,268,950,000	$10,903,425,000	$3,652,510,000	$7,305,020,000	$10,957,530,000

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 3: Deceptive Trade and False Claims Penalties - Multi-Source Drugs

		Analysis Using ASP		*Analysis Using AWP Thresholds*[1]			*Penalties (ASP and (AWP - 20.0%))*			*Penalties (ASP and (AWP - 66.0%))*		
	Total # of Claims	# of Claims Used in ASP Analysis	# of Fraudulent Claims	# of Claims Used in AWP Threshhold Analysis	# of Fraudulent Claims Based on (AWP-20.0%)	# of Fraudulent Claims Based on (AWP-66.0%)	Deceptive Trade ($2500/claim)	False Claim ($5000/claim)	Total Penalties	Deceptive Trade ($2500/claim)	False Claim ($5000/claim)	Total Penalties
State Complaint												
Amgen	156	0	0	156	128	152	$320,000	$640,000	$960,000	$380,000	$760,000	$1,140,000
AstraZeneca	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Aventis Group	26	0	0	26	0	6	$0	$0	$0	$15,000	$30,000	$45,000
Boehringer Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Braun	4,041	0	0	4,041	1,703	3,031	$4,257,500	$8,515,000	$12,772,500	$7,577,500	$15,155,000	$22,732,500
Fujisawa Group	30	0	0	30	0	2	$0	$0	$0	$5,000	$10,000	$15,000
Immunex	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Johnson & Johnson	4,349	1,340	1,080	3,009	2,770	2,949	$9,575,000	$19,150,000	$28,725,000	$10,022,500	$20,045,000	$30,067,500
Novartis	9,290	0	0	9,290	5,655	8,495	$14,137,500	$28,275,000	$42,412,500	$21,297,500	$42,475,000	$63,712,500
Pfizer	454	0	0	454	450	451	$1,125,000	$2,250,000	$3,375,000	$1,127,500	$2,255,000	$3,382,500
Schering-Plough Group	91,927	78,531	77,447	13,396	10,489	13,223	$219,840,000	$439,680,000	$659,520,000	$226,675,000	$453,350,000	$680,025,000
Sicor Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Watson	22,343	0	0	22,343	11,316	20,747	$28,295,000	$56,590,000	$84,885,000	$51,867,500	$103,735,000	$155,602,500
Total State Complaint	132,616	79,871	78,507	52,745	32,513	49,056	$277,550,000	$555,100,000	$832,650,000	$318,907,500	$637,815,000	$956,722,500
Federal Complaint												
Abbott	5,430	0	0	5,430	4,210	4,982	$10,525,000	$21,050,000	$31,575,000	$12,455,000	$24,910,000	$37,365,000
Baxter	3,776	0	0	3,776	589	2,933	$1,722,500	$3,445,000	$5,167,500	$7,332,500	$14,665,000	$21,997,500
BMS Group	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Dey	35,154	0	0	35,154	11,621	27,521	$29,052,500	$58,105,000	$87,157,500	$68,802,500	$137,605,000	$206,407,500
Pharmacia Group	60	13	3	47	1	3	$10,000	$20,000	$30,000	$15,000	$30,000	$45,000
TAP	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Total Federal Complaint	44,420	13	3	44,407	16,521	35,439	$41,310,000	$82,620,000	$123,930,000	$88,605,000	$177,210,000	$265,815,000
Bayer Complaint												
Bayer	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Total Bayer Complaint	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0
Total-All Defendants	177,036	79,884	78,510	97,152	49,034	84,495	$318,860,000	$637,720,000	$956,580,000	$407,512,500	$815,025,000	$1,222,537,500

Notes:
1. Total Number of claims used in the AWP threshold analysis will not equal the sum of fraudulent claims found using the different AWP thresholds.

Table 4: Summary of Overcharge Damages and Penalties by Defendant and Total

	All Overcharges[1]	*Penalties - Based on Yardstick Threshold Bounds*[2] Lower Bound	Upper Bound
State Complaint			
Amgen	$0	$19,387,500	$20,310,000
AstraZeneca	$11,245	$1,016,355,000	$1,019,535,000
Aventis Group	$4,092	$581,317,500	$583,387,500
Boehringer Group	$0	$0	$0
Braun	$0	$12,772,500	$22,732,500
Fujisawa Group	$0	$3,390,000	$3,502,500
Immunex	$0	$292,500	$292,500
Johnson & Johnson	$37,783	$1,889,067,500	$1,920,637,500
Novartis	$0	$1,032,637,500	$1,057,822,500
Pfizer	$0	$2,938,875,000	$2,949,990,000
Schering-Plough Group	$1,281,415	$1,629,705,000	$1,652,940,000
Sicor Group	$0	$0	$0
Watson	$0	$84,922,500	$155,640,000
Total State Complaint	$1,334,535	$9,218,722,500	$9,386,790,000
Federal Complaint			
Abbott	$0	$143,535,000	$150,427,500
Baxter	$0	$5,910,000	$22,740,000
BMS Group	$9,134	$1,486,957,500	$1,494,990,000
Dey	$0	$67,157,500	$206,407,500
Pharmacia Group	$559	$369,022,500	$369,465,000
TAP	$0	$249,550,000	$249,825,000
Total Federal Complaint	$9,693	$2,342,242,500	$2,493,855,000
Bayer Complaint			
Bayer	$0	$299,040,000	$299,422,500
Total Bayer Complaint	$0	$299,040,000	$299,422,500
Total-All Defendants	$1,344,228	$11,860,005,000	$12,180,067,500

Notes:
1. Table 1.
2. Tables 2 and 3.

Table 5: Deceptive Trade and False Claims Penalties - Innovator and Multi-Source Drugs (Statute Change)

		Analysis Using ASP			*Analysis Using AWP Statute*			*Innovator Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Multi-Source Penalties (ASP and Statute Change in July 2002 from AWP - 10% to AWP - 15%)*			*Total Statute Penalties*
	Total # of Claims	# of Claims Used in ASP Analysis[1]	# of Fraudulent Claims (Innovator)[2]	# of Fraudulent Claims (Multi-Source)[3]	# of Claims Used in AWP Threshhold Analysis[4]	# of Innovator Fraudulent Claims Based on Statute (10% - 15%)[5]	# of Multi-Source Fraudulent Claims Based on Statute (10% - 15%)[6]	Deceptive Trade ($2500/claim)	False Claim ($5000/claim)	Total Penalties	Deceptive Trade ($2500/claim)	False Claim ($5000/claim)	Total Penalties	Total Penalties
State Complaint														
Amgen	3,005	0	0	0	3,005	2,295	117	$5,737,500	$11,475,000	$17,212,500	$292,500	$585,000	$877,500	$18,090,000
AstraZeneca	141,150	4,129	3,627	0	137,021	125,768	0	$323,487,500	$646,975,000	$970,462,500	$0	$0	$0	$970,462,500
Aventis Group	82,028	12	12	0	82,016	75,852	0	$189,660,000	$379,320,000	$568,980,000	$0	$0	$0	$568,980,000
Boehringer Group	0	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0	$0
Braun	4,041	0	0	0	4,041	0	1,202	$0	$0	$0	$3,005,000	$6,010,000	$9,015,000	$9,015,000
Fujisawa Group	609	0	0	0	609	442	0	$1,105,000	$2,210,000	$3,315,000	$0	$0	$0	$3,315,000
Immunex	157	0	0	0	157	33	0	$82,500	$165,000	$247,500	$0	$0	$0	$247,500
Johnson & Johnson	275,272	1,823	396	1,060	273,449	237,477	2,683	$594,682,500	$1,189,365,000	$1,784,047,500	$9,357,500	$18,715,000	$28,072,500	$1,812,120,000
Novartis	154,718	0	0	0	154,718	129,674	5,325	$324,185,000	$648,370,000	$972,555,000	$13,312,500	$26,625,000	$39,937,500	$1,012,492,500
Pfizer	420,270	0	0	0	420,270	382,108	446	$955,270,000	$1,910,540,000	$2,865,810,000	$1,115,000	$2,230,000	$3,345,000	$2,869,155,000
Schering-Plough Group	228,477	82,747	4,001	77,447	145,730	122,213	7,400	$315,535,000	$631,070,000	$946,605,000	$212,117,500	$424,235,000	$636,352,500	$1,582,957,500
Sicor Group	0	0	0	0	0	0	0	$0	$0	$0	$0	$0	$0	$0
Watson	22,348	0	0	0	22,348	5	8,908	$12,500	$25,000	$37,500	$22,265,000	$44,530,000	$66,795,000	$66,832,500
Total State Complaint	1,332,075	88,711	8,036	78,507	1,243,364	1,075,867	26,079	$2,709,757,500	$5,419,515,000	$8,129,272,500	$261,465,000	$522,930,000	$784,395,000	$8,913,667,500
Federal Complaint														
Abbott	23,231	0	0	0	23,231	14,431	3,705	$36,077,500	$72,155,000	$108,232,500	$9,262,500	$18,525,000	$27,787,500	$136,020,000
Baxter	4,367	0	0	0	4,367	93	587	$232,500	$465,000	$697,500	$1,417,500	$2,835,000	$4,252,500	$4,950,000
BMS Group	213,887	482	428	0	213,405	181,626	0	$480,135,000	$960,270,000	$1,440,405,000	$0	$0	$0	$1,440,405,000
Dey	35,154	0	0	0	35,154	0	9,872	$0	$0	$0	$24,680,000	$49,360,000	$74,040,000	$74,040,000
Pharmacia Group	51,603	13	0	3	51,590	46,669	0	$116,722,500	$233,445,000	$350,167,500	$7,500	$15,000	$22,500	$350,190,000
TAP	34,847	0	0	0	34,847	31,281	0	$78,202,500	$156,405,000	$234,607,500	$0	$0	$0	$234,607,500
Total Federal Complaint	363,089	495	428	3	362,594	284,120	14,144	$711,370,000	$1,422,740,000	$2,134,110,000	$35,367,500	$70,735,000	$106,102,500	$2,240,212,500
Bayer Complaint														
Bayer	41,162	0	0	0	41,162	39,206	0	$98,015,000	$196,030,000	$294,045,000	$0	$0	$0	$294,045,000
Total Bayer Complaint	41,162	0	0	0	41,162	39,206	0	$98,015,000	$196,030,000	$294,045,000	$0	$0	$0	$294,045,000
Total-All Defendants	1,736,326	89,206	8,464	78,510	1,647,120	1,399,193	40,223	$3,519,142,500	$7,038,285,000	$10,557,427,500	$296,832,500	$593,665,000	$890,497,500	$11,447,925,000

Notes:
1. Tables 2 and 3.
2. Table 2.
3. Table 3.
4. Tables 2 and 3.
5. Table 2.
6. Table 3.